MINUTES OF 289th MEETING OF REGISTRATION BOARD HELD ON 14th-16th MAY, 2019

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

289th meeting of Registration Board was held on 14–16th May, 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. The meeting was attended by following:-

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

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. Dr. Hafsa Karam Ellahi (Additional Director, QA&LT) assisted by respective Assistant Director, presented the agenda of QA & LT Division.

Mr. Shamim Ahmad, Mr. Hamid Raza, Mr. Arshad Mehmood (PPMA), Mr.Rashid Mureed & Mr. Nadeem Alamgeer (Pharma Bureau) and Mr. M.Asad Malik (PCDA) attended the meeting as observers.

Item No. I: Confirmation of Minutes of 288th Meeting of Registration Board.

288th meeting of Registration Board was held on 14th to 15th February 2019. The draft minutes of 288th meeting of Registration Board were circulated among the members of the meeting on 18th March, 2019 with the request to forward their comments (if any) within five days. None of the members disagreed the draft minutes. Accordingly, minutes were approved by the Chairman Registration Board and circulated to all concerned.

Decision: Registration Board confirmed minutes of 288th meeting.

Item No. II: Cases Referred by Members of Registration Board.

A. Dr. Amanullah Khan, Director DTL, Quetta.

1. Email of May 3, 2019

Comment	Response
As earlier through email and during various meetings I have pointed out my serious concern over the way the panels are constituted for inspection within the country and outside the country because such panels are not acceptable to me because to me it's violation of the law as the panels for inspection are not approved by the board rather it is constituted by only one individual which is based by personal pick and choose and is against the teachings of our Prophet Hazarat Muhammad (P.B.U.H). Therefore across the board all those Inspection's which are done or going to be done without the approval of the Registration Board for me they are not Approved. In the each decision of the panel inspection my note of dissent shall be added and read as not Approved	Matter has already been deliberated at length and decided in 286th meeting Registration Board held on 14-16th November, 2018.

2. Email of January 26, 2018

a. Biological Drugs Registration.

It is submitted with great concerned that in my opinion the Biological Division has few very important issues which relates with the working capacity of the division and other issues related with DRAP and Board.

a. Biological Drugs Registration:

S.No.	Comment	Response
1.	It is submitted with great concerned that in my opinion the Biological Division has few very important issues which relates with the working capacity of the division and other issues related with DRAP and Board.	**Reply of DBER:** 1.1 The working in the DBER has improved tremendously after the appointment of permanent Director with relevant experience which has been duly acknowledged by Dr. Amanullah on different occasions. 1.2 Biological Drug is a highly specialized rapidly evolving subject; therefore the DRAP Policy Board in its first meeting in 2013 had rightly approved the formation of a separate registration board. This decision has been acknowledged by the present Registration Board many times. When this decision is implemented the Biological Drugs Board will engage the relevant experts in the field of oncology, vaccinology, hematology, endocrinology, virology, bacteriology, biotechnology, epidemiology, biotechnology quality control and manufacturing expertise etc. for both human and veterinary biological drugs. 1.3 In DRAP fresh 100 Assistant Directors were recruited who are still undergoing trainings for evaluation of dossiers, majority have no relevant experience in manufacturing or quality control of drugs let alone biological drugs. 1.4 It takes years of teaching to become knowledgeable in the field of biological drugs as this subject is not taught in practical terms in any university or college of our country at graduate of masters level. Initially 09 Asst. Directors were appointed in DBER. Out of which 04 were latter on transferred to NCLB and 01 was transferred to CDL, Karachi. The 04 transferred to NCLB were later on transferred to Health & OTC Division which were then transferred to other divisions. Out of remaining 04 Asst. Directors, 01 was recently transferred to Pharmaceutical Evaluation Cell after working in DBER for

		more than two years. All this is happening without the consent of Director DBER who is currently working with only 03 Asst. Directors instead of full strength. 1.5 Now, the renewal cases are also being referred to Biological drugs from RRR section and due to work load and less human resource the timely processing of renewal applications is becoming really difficult. 1.5. Despite such work load and limited human resource the Biological Drugs Division has no pendency of new registration applications and is able to achieve many mile stones shown below. **Further deliberations in Registration Board:** For constitution of separate Board for Biological drugs, the Board advised to process case at appropriate forum. Appropraite distribution of human resource is primalrily function and responsibility of the management of an organization. It would be appropriate that Biological Division may process case keeping in view existing workload of present officers and upcoming/ pending work to DRAP's management for suitable decision.
2.	The present staff is inexperienced due to which the biological product(s) case(s) are not properly presented before the registration board.	**Reply of DBER:** 2.1 In DRAP over 100 fresh Assistant Directors were recruited who are still undergoing trainings for evaluation of dossiers, majority have no relevant experience in manufacturing or quality control of drugs let alone biological drugs. 2.2 The cases are presented on approved format if there is any deficiency in the format the Board may review the pattern. 2.3As noted by Dr. Amanullah in previous meetings the working has improved after the appointment of permanent Director with relevant experience in vaccinology. 2.4 The incumbent Director being the only experienced person in the relevant field with this new staff has managed to achieve the following during the past one year: a. Developed the biosimilarity guidelines for registration of imported biotherapeutic products. b. Developed the biosimilarity guidelines for registration of locally biotherapeutic products. c. Developed the guidelines for registration of imported Enoxaparin Injections. d. Developed the guidelines for registration of locally manufactured Enoxaparin Injections. e. Processed the registration applications which were pending since 2013. 2.5. Moreover, it is evident by comparing the agenda of recent meetings with previous meetings that all the important information e.g. Biosimilarity studies, stability studies etc. as required by the Registration Board is included in the agenda of meeting. 2.6Further, now every registration application is being evaluated as per checklist of Form-5 or Form-5A and the checklists are attached with the applications or office files as permanent record of evaluation report while previously that was not the practice. 2.7. As compared to other drugs the Biological Drugs applications are already submitted on CTD dossiers for the past many years. This format is now being adopted for other drugs as well and after uniform assessment the Board will be able to

		judge all drugs on same criteria thus avoiding the present two systems of applications. **Further deliberations in Registration Board:** Registration Board considers abd decide the applications in light of available data and status of the product / formulation in reference regulatory authorities. If any case is deficient in any information / data, then such applications are deferred for having required data.
3.	After the resignation by the biological member from the registration board and to date no replacement of the biological member by the DRAP is done and it is one of the factor that the registration board has some difficulty in the grant of registration for biological products, so there is immediate need to nominate biological expert/ member so the registration of the biological products becomes smooth.	**Reply of DBER:** 3.1 The Biological Drugs Division has already forwarded the file for nomination of another expert on 05-05-2017. The nomination is still pending. 3.2 However, currently Dr. Qurban Ali and Maj. Gen. Tahir Mukhtar Sayed are the biological expert but it seems that Dr. Amanullah is not satisfied with their contribution. It is further clarified that both of these members were fully involved in the development of above guidelines. 3.3 Moreover, Directors of pharmaceutical Drug Testing Laboratories are the members of the Board while the relevant Director NCLB which is responsible for the Lot release of Biological Drugs is not the member of the Board it is once again submitted that Director NCLB should be part of the DRB on permanent basis. **Further deliberations in Registration Board:** Point at 3.2 above was refuted by Director DTL, Quetta and other members of Registration Board.
4.	Unfortunately non-technical persons are nominated in the panel for inspection biological products/units abroad which is not in the public interest and it is because that the registration board is not allowed to constitute panel of experts that is right person for a right job rather it is based on pick and choose and favoritism simply to accommodate each other.	**Reply of DBER:** 4.1 Initially there was a committee for constitution of panel for inspection abroad which included the concerned Director DBER along with Director PE&R and was Chaired by CEO, DRAP. But currently, the DBER refers the cases to Director DPER for constitution of panel. 4.2 The list of past inspections may be presented in the board and made part of minutes. **Further deliberations in Registration Board:** Matter for constitution of panel has has already been deliberated at length and decided in 286th meeting Registration Board held on 14-16th November, 2018. Chairman, Registration Board dispelled the impression about nomination of non-technical members in such inspection. He shared that for inspection aborad panel comprises of 02 relevant experts taken from DRAP's statutory Boards and senior officers of DRAP having sufficient knowledge and experience. All these nominations are endorsed by CEO, DRAP and administratively approved by Secretray, M/o NHSR&C. During meeting, data of inspections (panel members, manufacturing sites inspected, name of molecule(s)/ product(s) and decision) conducted during 2017 and 2018 was also shared with Director DTL, Quetta for further query (if any).
5.	As we know that at Government level we have some visa problem with our neighboring importing county (India) so it is proposed that if any WHO Prequalified biological products coming from that manufacturing site or if any biological product of that particular manufacturing site is already	**Reply of DBER:** The matter is related to current Import Policy for finished drugs. However, as per current policy if a plant has been inspected for a particular type of product, the exemption may be granted for the same type of product within 05 years of inspection. **Further deliberations in Registration Board:** In addition to above, all products either pre-qualified by WHO or approved by reference regulatoty authorities are exempted

	registered with DRAP I think we can exempt inspection abroad of that manufacturing site(s) in the public interest as to ensure availability of that drug for our people.	from inspection of manufacturer.

b. Manufactures Abroad Inspection Reports

Comment	Response
Reference to my couple of Note of dissents regarding unlawful constitution of panel of experts for inspection locally and abroad for the Product specific Inspection and GMP of the manufacturer. It is observed with great concerned that the August board members are never appraised about the inspection reports of manufacturers abroad. I strongly demand that all the manufacturers abroad inspection reports should be shared with the august board members for the final approval of the products likewise the local manufacturer products inspection reports and products are discussed for final approval or otherwise. The imported products/ molecules are initially discussed in the board and its approval is subject to inspection report but unfortunately the abroad inspection reports are never discussed in the board. It is also demanded that the board should be appraised about the number of inspections abroad during the year 2018, like name of molecule(s)/ product(s), Name of the inspectors and country of import conclusion of the panel.	Already responded in point 4 above.

B. Dr. Aslam Shah Member Registration Board, DRAP.

Comment	Response
Now a days majority of Oncology Pharmaceuticals are not available in market, even with it's authorized distirbuors & the Patients are suffering, because their Chemotherapy cycles are disturbing due to non availability of drugs. The local manufacturer Pharmadac Supplies are also short because of their production facility problems. The Anti cancer non availability problem is in now becoming chronic & I am expecting that very soon the Voice from Oncologist, Patients, & social media will be viral, so need immediate proactive actions to resolve this problem. I would request the Secretary & Chairman of Registration board to kindly look in to this matter to resolve on priority.	Keeping in view importance of the matter, Registration Board is already considering anti-cancer products on priority basis and applications submitted till December, 2018 has already been decided. The Board was apprised that some brands of anti-cancer drugs are in short supply / not available due to closure of their abroad manufacturing facilities either due to renovation or other organizational matters but other alternate brands / therapeutic equivalents are available. To cater such situation, DRAP is also granting permission for import of un-registered drugs for exclusive use of institutions and concerned DRAP field offices have been authorized for such granting such permissions. As far as matter of M/s Pharmaduc is concerned, the manufacturing facility is non-operative due to GMP non-compliance issues. Members were also requested to identify any non-available drug for taking up the matter accordingly. For this purpose, DRAP has already notified a committee on availability of drugs who work in close liason with manufacurers / importers, provincial governments, institutions etc.

ItemNo.III: Miscellaneous Cases:

Case No.01: World Health Organization (WHO) Collaborative Procedure for Accelerated Registration

Pakistan became signatory of WHO Collaborative Procedure for Accelerated Registration on 23rd February 2018. The collaborative registration procedure serves to facilitate and accelerate national registration of pharmaceutical products which the WHO Prequalification of Medicines Team (WHO/PQT) has already assessed and prequalified. Under this agreement, WHO/PQT assessment and inspection reports will be shared with DRAP on requirement. DRAP Authority in its 57th meeting held on 27th March, 2018 endorsed the signing of agreement between DRAP and WHO-PQ and gave its consent to proceed further.

Accordingly, PE&R division has prepared proposed steps for this procedure in light of WHO Technical Report Series (TRS) as follows:

1. The foreign company must have local agent/representative in Pakistan with valid drug sale license.
2. Applicants (companies) shall express interest (Submission of Expression of Interest) in applying the procedure for accelerated registration to their prequalified products. The applicant shall fill Appendix 3 Part A *(WHO TRS 996_2016)*.
3. Applicants authorize WHO to share its assessment and inspection outcomes for the specific product(s). The applicant shall fill Appendix 2 *(WHO TRS 996_2016)*.
4. The authorized representative (sole agent) must submit process Fee and the complete information required under Module 1 of DRAP CTD template (Appendix 1) *(WHO TRS 996_2016)*.
5. The authorized representative must also submit the complete CTD dossier with proof that same version was submitted to WHO along with any post registration variation thereunder.
6. DRAP shall communicate its decision on whether to apply the procedure and shall fill Appendix 3 Part B *(WHO TRS 996_2016)*.
7. If DRAP accepts to use the collaborative procedure, DRAP will complete evaluation process out of queue and communicate deficiencies/additional requirement within 30 days after submission.
8. In case any clarification required authorized representative (sole agent) must submit the complete reply within 30 days.
9. On-site inspection shall be exempted for all products under this procedure being WHO pre-qualified product.
10. Once Registration requirement are fulfilled by principle manufacturer through its authorized representative, DRAP will complete registration process within 60 Days after final submission. DRAP shall communicate its decision to accept/ reject registration of the product also using Appendix 3 Part C. However, the pricing may take additional days.
11. Registration shall be granted for 5 years until and unless cancelled or revoked by Registration Board.
12. In situations where the applicant intended to apply the procedure to a registration application which is already pending with DRAP, the applicant should first update the dossier to ensure that the technical part of the information is the same as that submitted to WHO. The applicant shall fill Appendix 2 and Appendix 3 Part A *(WHO TRS996_2016)*.
13. All post-prequalification variations submitted to WHO shall be submitted simultaneously to the DRAP.

Decision: **Registration Board appreciated steps taken by DRAP for adopting internationally harmonized regulation and signing agreement with international health partners. The Board also endorsed above above procedure which is in line with WHO Technical Report Series (TRS).**

Case No. 02 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 was forwarded to the European Commission, which issued a final legally binding decision on 14 February 2019 for Quinsair and on 11 March 2019 for other quinolone and fluoroquinolone antibiotics given by mouth and by injection, which is 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.. Medicines and Healthcare products Regulatory Agency (MHRA) of UK also decided to adopt the decision of EC as a result of the EMA review.

Quinolone- and fluoroquinolone-containing medicinal products

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.

Decision: Keeping in view status of product in reference regulatory authorities, Registration Board decided as follows:

- **to initiate process / issuance of show cause for suspension / cancellation of first generation quinolones (cinoxacin, flumequine, nalidixic acid and pipemidic acid) due to serious safety concerns in injectable, oral and inhalational formulations.**
- **To update indications of second generation fluoroquinolones for consideration of Registration Board.**

Case No.03: De-Registration of Dettol Liquid (Reg. No.000150) – M/s Reckitt Benckiser Pakistan Ltd, Karachi

M/s Reckitt Benckiser Pakistan Ltd, Karachi has informed that Dettol Liquid, Reg. No.000150 registered in April, 1976 as per Drugs Act 1976 (―Act‖) as an antiseptic and disinfectant. However as per promulgation of DRAP Act, 2012 disinfectants belong in ―health and OTC products (non –drugs)‖catetory. This category is now headed by a separate Directorate Health & OTC products (non-drugs) for which registration and licensing is done separately for which the OTC Enlistment Rules are soon to be notified.

Dettol is a world famous brand used by general population for personal cleaning and hygiene since generations. The proposed OTC Enlistment Rules clearly states, as per definition para (d) and (i), as follows;

(d) "Disinfectant" means a health product or ingredient used for destroying or inhibiting micro –organisms that may b harmful to humans or animals. Disinfectants also include ingredients or products having additional antiseptic activity.

(i) "Health products" means Health and OTC products (non-drugs) as denined in the Act and include pro-biotics, disinfectants, food supplements, nutritional products, baby milk and foods, medicated cosmetics, medicated soaps, medicated shampoos, medical plasters and derma-care products or any other which may be notified in official gazette y DRAP as Health and OTC products;

Also as per the National Essential medicines List of Pakistan, Ministry of Health, Government of Pakistan – 2007 list, clause number 15.2, chloroxylenol 4.8% is included as a disinfectant. The present usage of their product Dettol ASL (after dilution) as per a local study conducted by M/s TNS Aftab& Associates in 2010, is as follows;

- Bathing – 80%
- Cuts & Bruises – 58%
- Washing clothes – 58%
- Shaving – 45%
- Nappies cleaning – 31%
- Allergy – 20%
- Floor Cleaning – 12%
- Kitchen slab cleaning – 9%
- Bathroom cleaning – 8%

The above data clearly delineates that the product usage is OTC unlike any medicine by general public and not requiring any prescription by physicians. The study in its entirety is attached for perusal.

Their product Dettol ASL is also amenable to Sales Tax on goods under the Sales Tax Act, 1990 while all products registered under the Drugs Act, 1976 are exempt from sales tax. An exception has been created for those products that are registered under the Act but are disinfectants. Their product, is therefore, also treated as a disinfectant by all taxing authorities.

That all that is sated above categorically demonstrates that their product, Dettol ASL is a disinfectant under the Act and clearly falls under the sub-category of Health and OTC products (Non-Drugs) under the DRAP Act. This sub-category is now liable to be treated separately under the OTC Rules, as it is presumed there will be less stringent regulation for those products that are not life saving or therapeutic drugs, for which an entirely separate Directorate has been created.

Therefore, by enlistment of their product they would continue paying GST along with deregulation and de-registration by DRAP from the general category and eventual enlistment and registration in the specific sub-category they fall within. This will enable their consumers to continue their endeavors in attaining health and hygiene resulting in;

- Maintaining continuous revenue for the government
- Spreading of Health Education with ongoing projects like **—Save the Children"** with Government of Pakistan
- Their company has initiated various health and hygiene programs in **Schools and Hospitals** for the benefit of common people.

In view of the foregoing, they would humbly urge to look into the matter with the above facts mentioned which favor Dettol Antiseptic Liquid being enlisted separately as a Health & OTC product (non-drug) after which a fresh letter of registration and new MRP may be issued keeping the facts that it is not a life saving or essential therapeutic drug in mind.

Decision of M-245: *Registration Board deferred all products for personal hearing / presentation before Registration Board.*

M/s Reckitt Benckiser Pakistan Private Limited has filed a Civil Suit No.264-2016 by before the High Court of Sindh vs Federation of Pakistan and others and Sindh High Court has passed an order dated 29-04-2019 i.e., summarized as under:

> *"The plaintiff has impuged letter dated 07.07.2015 which has been issued in response to the Plaintiff's application dated 16.02.2015 whereby, they had requested the Drug Regulatory Authority to enlist their product covered by this suit under the alternative Medicines & Health Products Enlistment Rules, 2014. In the said letter it is stated by the DRAP that since the product in question has already registered under the Drug's Act 1976, hence, now, it cannot be enlisted under the 2014 Rules. On perusal of the said letter it appears that DRAP has not assigned proper reasons as to the objections raised by the Plaintiff vis-à-vis. the applicability of the DRAP Act, 2012. Since apparently proper reasons have not been assigned by DRAP through letter dated 07.07.2015, the matter is remanded to the Drug Regulatory Authority of Pakistan to decide the application of the Plaintiff with proper reasons after affording opportunity of hearing to the plaintiff and pass appropriate orders in accordance with law. Furthermore, such exercise be preferably carried out within a maximum of 60 days from today and till then, no coercive action shall be taken against the Plaintiff."*

Aforementioned in view, M/s Reckitt Benckiser Pakistan was called (vide letter dated 09-05-2019) for personal hearing before the Registration Board on 14-05-2019. However, the firm, vide their letter dated 13-05-2019, raised following objections to the contents of letter issued for personal hearing:

a. The High Court has not remanded the matter back to the Registration Board. You will note that the order makes specific reference to letter dated 07th July 2015.Such letter was issued by the Directorate Health & OTC Products (non-drugs).Therefore, the remand order is directed at the Directorate Health & OTC Products (non-drugs) and the personal hearing is to be conducted by officials of such Directorate.
b. Furthermore, the Registration Board is not a defendant in Suit No.264 of 2016. Defendant No.3 is the Director Health & OTC Products (Non-drugs) and Defendant No.4 is the Deputy Drug Controller Health & OTC Products (Non-drugs). The direction of the High Court in the Order is quite clearly issued to such Defendants and not to a party that is not a Defendant in the Suit.

Furthermore, the firm has also stated that:

1. Without prejudice to the above, the Company is also in the process of filing a High Court Apeal ("HCA") against the order of the High Court. It seeks reversal of the Order and suspension in the interim and shall, therefore, not enter any remand proceedings whether before the Registration Board or the Directorate Health & OTC Products (non-drugs) till such time that the HCA is first heard. Entering remand proceedings shall divest the Company of its right of impugning the remand order & you are, therefore, requested to permit the Company to exercise its statutory right of appeal for which it has 20days from the date of issuance of the Order under the law.
2. In the meanwhile you are requested to respond to our objections with reasons of alternatively, and ideally, to transfer the matter to the competent authority in light of Order of the High Court which has remanded the matter to and ordered that a personal hearing be granted by

the Directorate Health & OTC Products (Non-Drugs) (Defendant Nos. 3 & 4) and not the Registration Board.

3. Consequent to the above, internal and legal representatives of the Company will not be attending the personal hearing on the 14 May, 2019.

4. It may be noted that the company also reserves its right to file an appropriate application before the High Court in Suit No. 264 of 2016 in the event that the Registration Board proceeds any further in this matter.

Decision: Keeping in view the above mentioned sitauation, Registration Board decided to seek opinion of Legal Affairs Division, DRAP for further processing of case.

Case No.04. Risks & Concerns Associated with Dydrogesterone.

A number of applications have been received by Pharmaceutical Evaluation & Registration Division for registration of Dydrogesterone Tablets. While evaluation, it was identified that the applied formulations were based on "Cis Isomer" of Dydrogesteronei.e not in compliance with the USP monograph for dydrogesterone tablet & European Pharmacopeial monograph for dydrogesterone API, both of which state "trans isomeric form".

The observation was further confirmed by reviewing innovator's formulation approved by following Reference Regulatory Authorities:

a. ANSM France (Duphaston, Authorization Holder: MYLAN MEDICAL SAS)
b. CBGMEB Netherlands (Duphaston; Reg. No. RVG 107765/ 05619)
c. AGES Austria (Duphaston, Owner: BGP Products GmbH, Perfektastrasse 84A, 1230 Vienna, Austria)
d. Swissmedic Switzerland

Concerns Raised by Abbott Laboratories:

M/ s Abbott Laboratories (Pakistan) Ltd. has raised the same issue and highlighted following points of concern & risks associated with the use of mislabeled Dydrogesterone:

- Solvay Pharmaceuticals is the only company in the world which manufactures dydrogesterone because manufacturing requires a proprietary technique.
- In Pakistan, dydrogesterone was only marketed by Solvay's agents, Highnoon Laboratories Limited under the brand name of DUPHASTON i.e currently owned by Abbott Laboratories.
- Dydrogesterone manufacturing process involves, as an essential step, a photochemical reaction which leads to conversion of configuration. The manufacturing of 6-dehydroprogesterone lacks the photochemical conversion step resulting in substantially different 3D structure.
- Different structures lead to different pharmacological profile such that efficacy of these two molecules differ significantly.
- The clinical data on efficacy and/or safety is not available for 6-dehydroprogesterone lacking the proof that this is any beneficial for the patient. As there is no data in support of 6- Dehydroprogesterone, it cannot be evaluated in comparison to dydrogesterone in terms of safety & efficacy.

Furthermore, M/s Abbott has submitted following supportive studies:

i. Drug analysis conducted on products claiming as dydrogesterone at:
   1) Abbott's MS&T Analytical Sciences & Technology, Weesp, The Netherlands.
   2) Industrial Analytical Center, HEJ Research Institute of University, University of Karachi.

The results of the chemical analysis revealed the main component as 6-dehydroprogesterone & not dydrogesterone.

ii. Results Deduced From Comparative Molecular Modeling Study:

Dydrogesterone possesses a biological potency significantly higher than progesterone itself as it takes advantage both from its retro structure and from the presence of the C6-C7 double bond, which constricts the molecule into a rigid conformation probably suitable for the interaction with the progesterone receptor. Moreover, as a consequence of its better bioavailability and the progestational activity of its main metabolites (20-, 21- and 16-hydroxy derivatives), its equivalent dose, regarding the endometrial proliferation, is 10-20 times lower than that of progesterone itself**.**

Previous Proceeding:

In 2008 M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. Karachi, appealed before the Appellate Board against the decision of Registration Board regarding stoppage of production of their drug "Dirogest Tablets" containing "Dydrogesterone Cis Isomer", for local manufacture. The Appellate Board in its 134th meeting held on 17-06-2008 after considering the following arguments & merits of the case, accepted the appeal since no scientific evidence contravened the arguments made by M/s Zafa.

Mr. Muhammad Amin Khan, C.E.O., Mr. Jawad Amin Khan, MD, Mr.Muhammad Aslam Shah, GM Technical & Mr. Hassan Masood Naqvi, Assistant Sales Manager of the firm appeared before the Board on behalf of the firm & stated that "Dirogest Tablets" containing "Dydrogesterone Cis Isomer was registered in 2002 and since then they are marketing the said drug without any complaint from the doctors/ market. They had been selling more than 100000 packs per year & no complaint had been received about their efficacy. They further added that the said drug was also available in Israel & Syria. They informed the board that comparative study of the two different dosage of the drug had been conducted in John Hopkins Bloomberg School of Public Health and some trials in different hospitals in Pakistan had been conducted. They also informed the board that their drug was cheaper than its competitors in the market.

It is however, submitted that Duphaston is the proprietary name of the dydrogesterone containing product registered by Ministry of Health, Israel in the name of ABBOT MEDICAL LABRATORIES LTD, ISRAEL. Moreover, M/s Zafa, in order to prove their stance, is obliged to provide data regarding aforementioned comparative study.

Findings:

Besides progesterone, the natural progestational agent, many synthetic progestins are known. One of the classes is represented by “Retrosteroids” and the most representative compound among these is 6-dehydroretroprogesterone (dydrogesterone). Another progestin considered in this regard is 6-deydroprogesterone (Cis Isomer), having a molecular structure almost identical to that of 6-dehydroretroprogesterone (dydrogesterone), however in dydrogesterone molecule, the hydrogen atom at C-9 is at beta position & methyl group at C-10 is at the alpha position (Figure1). Whereas 6-Dehydroprogesterone has a reverse configuration at position C-9 & C-10 (Figure2), hence the term ‘retro’ progesterone. The acetyl group at C-17 in both structures have same configuration.

Structural Comparison of 6 – Dehydroprogesterone and Dydrogesterone

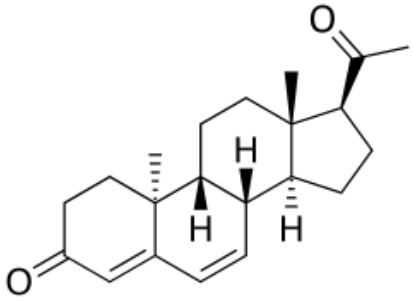

Figure1

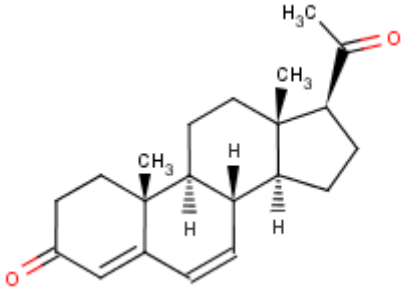

Figure 2

Both the isomers have different physical properties confirming these to be different pharmaceutical entities.

S.No.	Attributes	Cis Isomer	Trans Isomer
1	Chemical Name	6-Dehydroprogesterone	6-Dehydroretroprogesterone
2	Molecular Weight	312.45	312.45
4	CAS Number	1162-56-7	152-62-5
5	Specific Rotation	+170º- +182º	-469-485(dried substance) measured at 25ºC
6	Melting point	142-148ºC	167-171ºC
7	Relative Retention Time towards Dydrogesterone (Reverse phase HPLC with UV Detector) USP38-NF33	1.17 min	1min

The Registration Board in its 281st meeting deferred the case for final comments from PPMA. The board advised the observers of the PPMA to submit their response in the matter within 15 days without waiting for any letter from DRAP. Board further directed to present all the deferred cases in the next meeting.

Decision of M-284:

Registration Board deferred the case for final comments from PPMA. The board advised the observers of the PPMA to submit their response in the matter within 15 days without waiting for any letter from DRAP. Board further directed to present all the deferred cases in the next meeting.

In this regard, a reminder has also been issued to PPMA dated 22-10-2018 to comments within 07 days for consideration and finalization of the case by PPMA.

Decision of M-286: *Registration Board deliberated the case in the light of above stated facts and findings and decided as under:*

Since USP monograph for Dydrogesterone states CAS No. "152-62-5" i.e assigned to "Trans Isomeric Form; 6-Dehydroretroprogesterone" and as per Drugs Specification Rules 1978, "drug products registered with any official pharmacopoeial specifications shall follow specifications present in the latest edition of that publication". Furthermore, as per information

available on web, approval status of "Cis Isomeric Form" of dydrogesterone could neither be confirmed in any Reference Regulatory Authority nor in Syria and Israel. Therefore, the Board referred the case to the Appellate Board with the request to review the decision taken vide its 134th meeting, held on 17-06-2008.

Accordingly, the case was considered by the Appellate Board as per following details.

i. The representative of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, requested for adjournment.

ii. The Representative of M/s Abbott Laboratories Pakistan Ltd, contended that there are following differences Dydrogesterone and 6-Dehydroprogesterone.

Dydrogesterone (Duphaston)	**6-Dehydroprogesterone.**
Dydrogestrone is "Retro-Steroid" shaped by photochemical conversion (Trans-Isomer)	A synthetic derivative and natural metabolite of progesterone, a steroid isomer of Dydrogesterone but not retro-steroid (Cis-Isomer)
Due to Retro Steroidal nature it is highly selective for the progesterone receptor.	No such benefit is offered as the chemical structure is not retro-steroid.
Due to the retro-steroidal nature its metabolites are progestogenic	Non-retro-steroid are not only metabolized to a greater extent but also have a potential to generate in active metabolites with secondary effects that are non-progestrogenic.
As of April 22, 2019, 623 articles are available for the use of Dydrogestrone out of which 205 publications are clinical trials in humans.	Clinical data for use of 6-Dehydroprogesterone is lacking.
Extensive data and clinical experience world vide.	Due to lack of data there is a possibility of patient exposed to increased health risk or worsening of their medical condition.

iii. It was further argued that there are various companies promoting medicines containing 6-Dehydroprogeesterone but claiming that the active ingredient is Drydrogesterone and that they have the same indications, properties and action as Abbott's original molecule Dydrogesterone (Duphastan). The clinical data/study on the efficacy and safety is not available for 6-Dehydrogprogesterone. Available pre-clinical data is conclusive of the fact that 6-Dehydroprogesterone as a very low biological activity as compared to progesterone. In the absence of clinical data supporting the use of 6-Dehydroprogesterone, it cannot be evaluated if this molecule is comparable to Dydrogesterone in terms of safety and efficacy. Mislabeled dygrogesterone has not been fully tested for its safety or efficacy and therefore patient offered such medicines are not only exposed to increased health risks in terms of suboptimal effects leading to compromised health, but also to direct side effects. This further becomes point of concern in cases where with use of mislabeled products there is expected exposure to fetus.

iv. The Board considered the facts of the case and decided not to adjourned the hearing as requested by M/s Zafa Pharmnaceuticals Laboratories (Pvt) Ltd, Karachi, being a matter of public health importance. The board agreed with the scientific opinion/justification and interpretation of the drugs (Specifications) rules,1986 by the registration board in its 286th meeting held on 14th-16th November, 2018. The board directed the pharmaceutical Evaluation and Registration Division to ensure that all registered formulation/products and evaluation of Dydrogesterone products must comply with the official pharmacopeial monograph i.e USP. The board further directed the division of QA&LT to allow the import of API for registered products of Dydrogesterone as per official monograph only and to issue a circular for information of all concerned.

Decision: Registration Board advised to comply directions / decision of Appellate Board.

Case No. 05: Minutes of 07th Meeting of Expert Working Group on Veterinary Drugs Held on 13th May, 2019.

A. Use of multidose Oxytocin vials in Veterinary.

The meeting was conducted on the issue of alleged misuse of Oxytocin multi-dose vials in veterinary for the purpose of milk production. The matter was deliberated extensively by the participants. Decisions/discussion is as follow;

a. Dr. Muhammand Akram informed the committee that Oxytocin is, primarily, used in veterinary for the purpose of milk letdown. He further informed that the half life of Oxytocin Injection is around 02 minutes and withdrawal period of oxytocin in milk and meat is zero hours and zero days respectively. About 1-2cc of the injection is used for milk letdown.
b. The Committee/participants decided to expand the consultation horizon to a national consultation process/level and include the following relevant/technical experts in order to probe the matter in detail and a meeting in this regard shall be convened in near future;
    i. Human and veterinary Endocrinologists.
    ii. Expert from M/o. Food Security.
    iii. Director General's of livestock departments of all provinces.

Decision:- Registration Board endorsed the decision made in 07th meeting of Expert Working Group on Veterinary Drugs.

B. M/s. Mustafa Brothers, Faisalabad:

Importer and Manufacturer	**Brand Name and Composition**	**Decision of 269th meeting**
M/s. Mustafa Brothers 186-D, Peoples Colony No. 1, Faisalabad **Manufacturer:** M/s. Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI"ARRIAH") 600901, Russia, Vladimir region, Vladimir, microrayonYur' evets	**ARRIAH PPRV** (Virus vaccine against PesteDesPetitis Ruminants Cultural Dry) The Virus vaccine against PesteDesPetitis Ruminants Cultural Dry contains Peste Des Petitis Ruminants virus of "ARRIAH" strain. Each inoculating dose contains: PPRV vaccine strain "ARRIAH" not less than 1000$TCID_{50}$.	**269th** Registration Board approved the product as per import policy for finished drugs and as per valid legalized GMP & Free sale certificate **Approved**

Decision of 5th meeting of Expert working group: - Expert working group deferred the application for submission of exact strain name of PPRV virus used along with its scientific immunological relevance in Pakistan by the firm.

Now the firm has submitted the following reply.

a) PPRV "Virus Vaccine Against Peste Des Petits Ruminants Cultural Dry" strain clarification received from our manufacturer FGBI ARRIAH "Federal Center For Animal Health" Vladimir Russia is enclosed. The main virus of this vaccine strain is Nigeria 75/1 "ARRIAH" enclosed.
b) Publication ab2out PPRV "Virus Vaccine Against Peste Des Petits Ruminants Cultural Dry" manufactured by FGBI "ARRIAH" enclosed.
c) Scientific immunological relevance of PPRV "Virus Vaccine Against PesteDes Petits Ruminants Cultural Dry" in Pakistan "Nigeria 75/1" is attached:

For scientific immunological relevance in Pakistan, the firm has submitted a research article title,authors details,Abstract and its conclusion is reproduced as under.(The submitted article is annexed with the agenda**)**

"Peste des Petits Ruminants Vaccine
(Nigerian Strain 75/1) Confers Protection for at Least 3 Years in Sheep and Goats

Aamer Bin Zahur[1], Hamid Irshad[1], Aman Ullah[1], Muhammad Afzal[2], Asma Latif[1], RiasatWasee Ullah[1], Umer Farooq[1], Muhammad Humayoon Samo[2], Muhammad Jahangir[2], Giancarlo Ferrari[3], Manzoor Hussain[2], M. Munir Ahmad[4]

[1]Animal Health Research Laboratories, Animal Sciences Institute, national Agricultural Research Center, Islamabad, Pakistan
[2]FAO-UN Pakistan (GCP/PAK/127/USA) NARC, Park Road, Islamabad, Pakistan
[3]AGAH, FAO (Hq), Rome, Italy
[4]Divisional diagnostic Laboratory, Livestock and Dairy Development Department, Multan, Pakistan
Email: [*]hamidirshad@hotmail.com

Abstract

The present study reports the duration of immunity and protective efficacy of Peste des Petits Ruminants (PPR) vaccine (Nigerian strain 75/1) in sheep and goats. A total of 105 sheep and goats were divided into three groups A, B and C. Group A received normal recommended dose (1.0ml) of PPR vaccine, group B received half dose (0.5ml) of PPR vaccine and group C was kept as unvaccinated control group in contact with vaccinated animals. The post vaccination dynamics of antibodies against PPR virus was studied. It was found that significant antibody titres persisted for 3 years post vaccination in sheep and goats vaccinated with either full dose or half dose of PPR vaccine. The challenge protection studies were carried out in experimental animals at 24 and 36 month post vaccination. The vaccinates withstood challenge and were found completely resistant clinically and virologically to virulent PPR virus for 24 and 36 months post vaccination. The unvaccinated control animals developed typical clinical signs of PPR and the challenged virus was detected in ocular, nasal and oral secretions of these animals. This study demonstrated that a single immunization with PPR vaccine conferred solid protection in sheep and goats for 3 years.

Conclusion

The economic life of small ruminants is about 3 years. This study indicated that PPR vaccine (Nigerian strain 75/1) provides immunity for 3 years. Therefore, the strategic use of this vaccine will be useful in reducing the impact of infection in the areas where the disease is endemic."

Decision :

Expert working group noted that the Peste Des Petitis Ruminants (PPR) virus strainARRIAH is brand name of the Peste Des Petitis Ruminants (PPR) vaccine (Nigerian strain 75/1). The same strain is already registered in Pakistan therefore the working group recommended the veterinary vaccine i.e. ARRIAH PPRV by M/s. Mustafa Brothers, Faisalabad for registration and recommended the replacement of the word "ARRIAH" with "PPR vaccine (Nigerian strain 75/1)" in composition.

Decision:- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to approv the above mentioned product of M/s. Mustafa Brothers, Faisalabad with replacement of the word "ARRIAH" with "PPR vaccine (Nigerian strain 75/1)" in composition.

Item No. IV Division of Pharmaceutical Evaluation & Registration.

Pharmaceutcial Evaluation Cell (PEC)

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)

Case No. 03 Registration applications for local manufacturing of (veterinary) drugs

- **a.** New Cases
- **b.** Deferred Cases

Case No. 04 Registration applications of newly granted DML or New section (Veterinary)

- **a.** New DML /section
- **b.** Deferred Cases

Case No. 05 Registration applications of categories to be considered on priority

- **a.** Local manufacturing applications of priority categories defined by Registration Board in its 257th meeting
- **b.** Export facilitation
- **c.** Import applications of priority categories defined by Registration Board in its 257th meeting
  - i. Human
  - ii. Veterinary

Case No. 06 Registration applications of import cases

- **a.** New Cases (Human)
- **b.** New Cases (Veterinary)
- **c.** Deferred cases
  - i. Human
  - ii. Veterinary

Case No. 07 Registration applications of drugs for which stability study data is submitted

- **a.** New cases
- **b.** Deferred cases
- **c.** Verification of stability study data
- **d.** Exemption from onsite verification of stability data

Case No. 08 Miscellaneous cases

Sr. No	Name of Evaluator	Title
1.	Mr. Awais	**Evaluator PEC-I**
2.	Mr. Ammar Ashraf Awan	**Evaluator PEC-II**
3.	Mr. Muhammad Haseeb Tariq	**Evaluator PEC-III**
4.	Mst.Farzana Raja	**Evaluator PEC-IV**
5.	Mst. Iqra Aftab	**Evaluator PEC-V**
6.	Mr. Muhammad Umar Latif	**Evaluator PEC-VI**
7.	Mst. Sidra Khalid	**Evaluator PEC-VII**
8.	Mst. Haleema Sharif	**Evaluator PEC-VIII**
9.	Mr. Sarfraz	**Evaluator PEC-X**
10.	Mr. Haneef Ullah	**Evaluator PEC-XI**
11.	Syed Ajwad Bukhari	**Evaluator PEC-XII**
12.	Mst. Mehwish Javed Khan	**Evaluator PEC-XIII**
13.	Mr. Muhammad Ahsan Hafiz	**Evaluator PEC-XIV**

Evaluator PEC-II

Case no. 01 Registration Applications for Local Manufacturing of (Human) Drugs.

a. New Cases:

1.	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	Onran 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ondansetron as hydrochloride dihydrate …….4mg"
	Diary No. Date of R& I & fee	Dy. No 10161 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Oniron 4mg Tablets of M/s Genome Pharmaceuticals, (Reg.# 068374)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 20-2-2018, concluding as under: "Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012."
	Remarks of the Evaluator[II]	
	Decision: Approved.	
2.	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	Onran 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ondansetron as hydrochloride dihydrate …….8mg"
	Diary No. Date of R& I & fee	Dy. No 10162 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Oniron 8mg Tablets of M/s Genome Pharmaceuticals, (Reg.# 068375)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
3.	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	Fosvac 20mg Tablet
	Composition	"Each Tablet Contains: Fosinopril Sodium…20mg"
	Diary No. Date of R& I & fee	Dy. No 10164 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antihypertensive.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Not available
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else apply on form 5-D along with stability data.
	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 apply on relevant Form along with stability data.	
4.	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	Fosvac 10mg Tablet
	Composition	"Each Tablet Contains: Fosinopril Sodium…10mg"
	Diary No. Date of R& I & fee	Dy. No 10163 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antihypertensive.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Aksopril Tablets 10mg of M/s Akson Pharmaceutical (Pvt) Ltd (Reg.#023747)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
5.	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	Jormia XR 1000mg Tablet
	Composition	"Each Extended Release Tablet Contains: Metformin Hydrochloride…1000mg"
	Diary No. Date of R& I & fee	Dy. No 10160 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dowphage ER 1000mg Tablet of M/s Martin Dow Ltd. Karachi. (Reg.#081129)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
6.	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	Fosvac 40mg Tablet
	Composition	"Each Tablet Contains: Fosinopril Sodium…40mg"
	Diary No. Date of R& I & fee	Dy. No 10165 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antihypertensive.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference	Approved by MHRA of UK

	Regulatory Authorities	
	Me-too status (with strength and dosage form)	Not available
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else apply on form 5-D along with stability data shall be submitted. Upon communication of above observation firm has replied that We would like to inform you that we are working on Form 5D dossier of the subject product and will provide updated dossier once completed as required by your good office"
	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 apply on relevant Form along with stability data.	
7.	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	Anprox 500mg Tablets
	Composition	"Each Tablet Contains: Naproxen Sodium 547.74mg Eq. to Naproxen…500mg"
	Diary No. Date of R& I & fee	Dy. No 10153 dated 19-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nextar 500mg Tablets of M/s Novamed Pharmaceuticals (Reg.# 076824)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
8.	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	Anprox 250mg Tablets
	Composition	Each Tablet Contains: Naproxen Sodium 273.8mg Eq. to Naproxen…250mg
	Diary No. Date of R& I & fee	Dy. No 10152 dated 19-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nextar 250mg Tablets of M/s Novamed Pharmaceuticals (Reg.# 076823)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
9.	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	Lanzap 30mg Tablet
	Composition	"Each Oral Disintegrating tablet Contains: Lansoprazole enteric coated Pellets (8.5%) 352.94mg Eq. to Lansoprazole…30mg"

	Diary No. Date of R& I & fee	Dy. No 10157 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antacids
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's,20's & 30's; As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm or else apply on form 5-D along with stability data shall be submitted. Upon communication of above observation firm has replied that We would like to inform you that we are working on Form 5D dossier of the subject product ad will provide updated dossier once completed as required by your good office"
	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 apply on relevant Form along with stability data.	
10.	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	Lanzap 15mg Capsule
	Composition	"Each Delayed Release Capsule Contains: Lansoprazole enteric coated Pellets (8.5%) 176.47mg Eq. to Lansoprazole…15mg"
	Diary No. Date of R& I & fee	Dy. No 10154 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Getlanso Capsules 15mg of M/s Getz Pharmaceuticals. (Reg.# 061098)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
11.	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	Lanzap 30mg Capsule
	Composition	Each Delayed Release Capsule Contains: Lansoprazole enteric coated Pellets (8.5%) 352.94mg Eq. to Lansoprazole…30mg
	Diary No. Date of R& I & fee	Dy. No 10155 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Getlanso Capsules 30mg of M/s Getz Pharmaceuticals. (Reg.# 061099)

	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
12.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	S-Butamol Syrup
	Composition	"Each 5ml Contains: Salbutamol as Sulphate…2mg"
	Diary No. Date of R& I & fee	Dy. No 10310 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Selective β2 agonist
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Ezibreath Syrup of M/s Rock Pharmaceuticals Laboratories, (Pvt) Ltd., (Reg.# 064242)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 25-07-2017, recommending grant of renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
13.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Healkast 10mg Tablets
	Composition	"Each film coated Tablet Contains: Montelukast as sodium…10mg"
	Diary No. Date of R& I & fee	Dy. No 10313 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Leukotriene antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Montekast 10mg Tablets of M/s Global Pharmaceuticals. (Reg.# 032154)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
14.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Helakast 4mg Sachet
	Composition	"Each Sachet Contains: Montelukast as sodium …… 4mg"
	Diary No. Date of R& I & fee	Dy. No 10312 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Leukotriene antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Aerotel Sachet of M/s Highnoon Laboratories. (Reg.#044768)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	

	Decision:Approved.	
15.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Healtrem 80/480 mg Tablets
	Composition	Each film coated Tablet Contains: Artemether ……. 80mg Lumefantrine ……. 480mg
	Diary No. Date of R& I & fee	Dy. No 10314 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status (with strength and dosage form)	Artem -DS Plus Tablets 80/480 of M/s Hilton Pharma, Karachi (Reg.# 066843)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	In contrary to reference product recommended by WHO, which is available as uncoated tablet, you have applied for film coated tablet.
	Decision:Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.	
16.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	H-Fenac 100mg Tablets
	Composition	"Each film coated Tablet Contains: Aceclofenac…100mg"
	Diary No. Date of R& I & fee	Dy. No 10307 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form-5
	Finished product Specifications	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 (with strength and dosage form)	Aclofen Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg.# 068419)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	No USP or BP monograph is available for applied formulation.
	Decision:Approved with innovator's specification.	
17.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Alumag 200/200/20 mg Suspension
	Composition	"Each 5ml Contains: Aluminium Hydroxide…200mg Magnesium Hydroxide…200mg Simethicon……20mg"
	Diary No. Date of R& I & fee	Dy. No 10308 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status (with strength and dosage form)	Not verifiable

	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	
18.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Flutin 20mg Capsule
	Composition	"Each Capsule Contains: Fluoxetine as hydrochloride…20mg"
	Diary No. Date of R& I & fee	Dy. No 10309 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Flufend Capsules 20mg of M/s Friends Pharma (Pvt.) Ltd (Reg.# 044757)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
19.	Name and address of manufacturer / Applicant	M/s Heal Pharmaceuticals Pvt Ltd. W-33 Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Healsoda Sachet
	Composition	"Each 4gm Sachet Contains: Sodium bicarbonate …… 1.716gm Citric Acid …… 0.702gm Sodium Citrate …..0.613gm Tartaric Acid ……0.858gm"
	Diary No. Date of R& I & fee	Dy. No 10311 dated 20-03-2018 Rs.20,000/- 19-03-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status (with strength and dosage form)	Citro Soda sachet of M/s Abbott (Reg.#008749)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
20.	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	Azelin Nasal Spray

	Composition	"Each ml Contains: Azelastine Hydrochloride…1mg"
	Diary No. Date of R& I & fee	Dy. No 10131 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antiallergic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	15ml & 30ml; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Azosin nasal spray of M/s Sante (Reg.#025165)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-02-2018, concluding satisfactory level of compliance with cGMP guidelines as of today.
	Remarks of the Evaluator[II]	Firm has sterile Drops (ophthalmic, Ear & Nose) section as per submitted GMP inspection report.
	Decision:Approved with innovator's specification.	
21.	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	Crolate 20mg/ml Eye Drops
	Composition	"Each 1ml of Eye Drops Contains: Sodium Cromoglicate …… 20mg"
	Diary No. Date of R& I & fee	Dy. No 10132 dated 19-03-2018 Rs. 20,000/- Dated 19-03-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5ml, 10ml, 13.5ml & 15ml; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	CROMO-STULLN UD EYE DROPS of M/s Haroon Brothers, Karachi (Reg.#045720)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-02-2018, concluding satisfactory level of compliance with cGMP guidelines as of today.
	Remarks of the Evaluator[II]	Firm has sterile Drops (ophthalmic, Ear & Nose) section as per submitted GMP inspection report.
	Decision:Approved with innovator's specification.	
22.	Name and address of manufacturer / Applicant	"M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan"
	Brand Name +Dosage Form + Strength	G-pentin 300mg Capsule
	Composition	"Each Capsule Contains: Gabapentin…300mg"
	Diary No. Date of R& I & fee	Dy. No 10448 dated 21-03-2018 Rs. 20,000/- 20-03-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Gababion 300mg Capsules of M/s Merck Marker, Karachi (Reg.#045346)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-12-2017, concluding as under: "All the observations pointed out during the inspection were discussed with management and they assured for early

		compliance. Overall rating of GMP was found good at the time of inspection."
	Remarks of the Evaluator[II]	
	Decision:Approved.	
23.	Name and address of manufacturer / Applicant	"M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan"
	Brand Name +Dosage Form + Strength	G-pentin 100mg Capsule
	Composition	"Each Capsule Contains: Gabapentin…100mg"
	Diary No. Date of R& I & fee	Dy. No 10449 dated 21-03-2018 Rs. 20,000/- 20-03-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Gababion 100mg Capsules of M/s Merck Marker, Karachi (Reg.#045345)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
24.	Name and address of manufacturer / Applicant	"M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan"
	Brand Name +Dosage Form + Strength	Paradole 325/37.5 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Acetaminophen …… 325mg Tramadol hydrochloride ……37.5mg"
	Diary No. Date of R& I & fee	Dy. No 10447 dated 21-03-2018 Rs. 20,000/- 20-03-2018
	Pharmacological Group	Analgesic/Antipyretic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Distalgesic Tablet by M/s Atco Lab. Karachi. (Reg#073865)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
25.	Name and address of manufacturer / Applicant	"M/s Avant Pharmaceuticals. M-028 H.I.T.E, Lasbela, Balochistan"
	Brand Name +Dosage Form + Strength	Opin-F 6/25 mg Capsule
	Composition	"Each Capsule Contains: Olanzapine…6mg Fluoxetine as hydrochloride…25mg"
	Diary No. Date of R& I & fee	Dy. No 10446 dated 21-03-2018 Rs. 20,000/- 20-03-2018
	Pharmacological Group	Antipsychotic/Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dipof 6/25 mg capsule by M/s Global Pharmaceuticals (Reg#077900)
	GMP status	As recorded for above application

	Remarks of the Evaluator[II]	
	Decision:Approved.	
26.	Name and address of manufacturer / Applicant	"M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi"
	Brand Name +Dosage Form + Strength	Fonaz 15g Cream
	Composition	"Each gram contains: Bifonazole…10mg/g (1% w/w)"
	Diary No. Date of R& I & fee	Dy. No 10136 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	15gm; As per PCA
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mecze Cream by M/s Epoch Pharmaceuticals, Karachi (Reg#045341)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 01-10-2018, concluding good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
27.	Name and address of manufacturer / Applicant	"M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi"
	Brand Name +Dosage Form + Strength	Mycotrim 10g Cream
	Composition	"Each gram Contains: Clotrimazole ……. 10mg "
	Diary No. Date of R& I & fee	Dy. No 10135 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PCA
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Benestine Cream 1% by M/s Searle IV Solutions (Pvt.) Ltd, Karachi (Reg#078619)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
28.	Name and address of manufacturer / Applicant	"M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi"
	Brand Name +Dosage Form + Strength	Fuzid Cream
	Composition	"Each gram Contains: Fusidic Acid…20mg"
	Diary No. Date of R& I & fee	Dy. No 10133 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per PCA
	Approval status of product in Reference Regulatory Authorities	Fucidin H cream of M/s LEO Laboratories Limited, approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mirazym Cream of M/s Hiranis Karachi (Reg.# 076516)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	

29.	Name and address of manufacturer / Applicant	"M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi"
	Brand Name +Dosage Form + Strength	Virolex Ointment
	Composition	"Each Gram Contains: Acyclovir…0.05gm "
	Diary No. Date of R& I & fee	Dy. No 10134 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per PCA
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Virolite Ointment 5 % M/s Pearl Pharmaceuticals (Reg.# 072032)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
30.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Aqua Mac 10ml Injection
	Composition	"Each Ampoule Contains: Sterile Water for Injection …….10ml"
	Diary No. Date of R& I & fee	Dy. No 9994 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Sterile pharmaceutical solvent & Diluting agent
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10ml x 1's & 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Water for Injection by M/s Pulse Pharmaceuticals (Reg#069217)
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
31.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Levosearl 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…500mg"
	Diary No. Date of R& I & fee	Dy. No 9996 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; Rs. 1095/-
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Tablets 500mg of M/s Actavis Group United Kingdom (MHRA Approved)
	Me-too status (with strength and dosage form)	Leflox Tablets 500mg of M/s Getz Pharma
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
32.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Levosearl 250mg Tablet

	Composition	"Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg"
	Diary No. Date of R& I & fee	Dy. No 9995 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; Rs. 545/-
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Tablets 250mg of M/s Actavis Group United (MHRA Approved)
	Me-too status (with strength and dosage form)	Leflox Kingdom Tablets 250mg of M/s Getz Pharma
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
33.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Tcosmid 50mg Tablet
	Composition	"Each film coated tablet Contains: Lacosamide…50mg"
	Diary No. Date of R& I & fee	Dy. No 9998 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	14's; Rs. 238/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Lacolep by M/s Hilton (Reg.#073857)
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
34.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Tcosmid 100mg Tablet
	Composition	"Each film coated tablet Contains: Lacosamide…100mg"
	Diary No. Date of R& I & fee	Dy. No 9999 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	14's; Rs. 364/-
	Approval status of product in Reference Regulatory Authorities	Vimpat oral tablet of UCB Inc, **USFDA**
	Me-too status (with strength and dosage form)	Lacolep tablet of Hilton Pharma (Reg # 073858)
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
35.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Tcosmid 150mg Tablet
	Composition	"Each film coated tablet Contains: Lacosamide…150mg"
	Diary No. Date of R& I & fee	Dy. No 10000 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Anti-epileptic

	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	14's; Rs. 532/-
	Approval status of product in Reference Regulatory Authorities	Vimpat 150mg Tablet of UCB, approved by USFDA
	Me-too status (with strength and dosage form)	Lacolep of M/s Hilton (Reg.#073859)
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
36.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	VD3 Capsule
	Composition	"Each Capsule Contains: Cholecalciferol (Vitamin D)…50,000 IU Eq. to 1mg"
	Diary No. Date of R& I & fee	Dy. No 9997 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Vitamin D3 analogue
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5's; Rs. 175/- 30's; Rs. 240/-
	Approval status of product in Reference Regulatory Authorities	Vitamin D capsule approved by USFDA
	Me-too status (with strength and dosage form)	Not available
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[II]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting, since submitted reference by firm contains "Ergocalciferol" instead of "Cholecalciferol".
	Decision:Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
37.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar"
	Brand Name +Dosage Form + Strength	Artimark 120mg Dry Injection
	Composition	"Each vial contains: Artesunate sterile powder……120mg"
	Diary No. Date of R& I & fee	Dy. No 9991 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	As fixed by Government
	Approval status of product in Reference Regulatory Authorities	WHO prequalified formulation
	Me-too status (with strength and dosage form)	Gen-M Injection by M/s Genix Pharma Karachi (Reg#076073)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML

	Remarks of the Evaluator[II]	
	Decision:Approved.	
38.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar"
	Brand Name +Dosage Form + Strength	Schizomark 25mg Tablet
	Composition	"Each film coated Tablet Contains: Quetiapine as Fumerate…25mg"
	Diary No. Date of R& I & fee	Dy. No 9992 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's & 30's; As fixed by Government
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Quit 25mg Tablets of M/s Navegal Laboratories, (Reg.# 068244)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator[II]	Firm had initially applied for extended release tablets with brand name of "Quewel XR 25mg Tablet". Subsequently firm has submitted revised formulation for film coated immediate release tablets, as per the reference product, along with fee of Rs. 5,000/- vide deposit slip# 1914553 dated 25-03-2019 for revision of formulation.
	Decision:Approved.	
39.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar"
	Brand Name +Dosage Form + Strength	Quewel XR 100mg Tablet
	Composition	"Each film coated Tablet Contains: Quetiapine as Fumerate…100mg"
	Diary No. Date of R& I & fee	Dy. No 9993 dated 16-03-2018 Rs.20,000/- 15-03-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's & 30's; As fixed by Government
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Qusel tablet 100mg of M/s Hilton Pharma
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator[II]	Firm had initially applied for extended release tablets with brand name of "Quewel XR 100mg Tablet". Subsequently firm has submitted revised formulation for film coated immediate release tablets, as per the reference product, along with fee of Rs. 5,000/- vide deposit slip# 1914553 dated 25-03-2019 for revision of formulation.
	Decision:Approved.	
40.	Name and address of manufacturer / Applicant	"M/s Sunrise Pharma Pvt Ltd. 594-A, Sundar Industrial Estate, Raiwind Road, Lahore **contract manufacturing by** M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	VD3 Injection

	Composition	"Each injection Contains: Cholecalciferol (Vitamin D3)…200,000 IU Eq. to 5mg/ml"
	Diary No. Date of R& I & fee	Dy. No 9986 dated 16-03-2018 Rs.50,000/- Dated 15-03-2018
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5's; Rs. 145/- 30's; Rs. 725/- As per SRO
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 GOOD 200,000 IU / 1 ml IM solution for injection ANSM, France approved
	Me-too status (with strength and dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	GMP Certificate issued on 15-03-2018 to M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore
	Remarks of the Evaluator[II]	
	Decision:Approved.	
41.	Name and address of manufacturer / Applicant	"M/s Perk Pharma Pvt Ltd. Plot # 197/1-B, Main Road, Industrial Estate Gadoon, Sawabi, Kpk"
	Brand Name +Dosage Form + Strength	Percip 250mg Tablet
	Composition	"Each film coated tablet Contains: Ciprofloxacin as hydrochloride …250mg"
	Diary No. Date of R& I & fee	Dy. No 10143 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin tablets 250mg of M/s Special Concept Development (UK MHRA Approved)
	Me-too status (with strength and dosage form)	Axcin Tablets 250mg of M/s Novartis Pharmaceuticals
	GMP status	Firm has submitted copy of GMP inspection report conducted on 8/1/2018, concluding as under: "All the observations in the inspection are discussed with the firm. They are committed to rectify all the observations. The firm may be considered to be operating in satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	
	Decision:Approved.	
42.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name +Dosage Form + Strength	Azibar 250mg Capsule
	Composition	"Each Capsule Contains: Azithromycin Dihydrate Eq. to Azithromycin…250mg"
	Diary No. Date of R& I & fee	Dy. No 11151 dated 27-03-2018 Rs.20,000/- 27-03-2018
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3's,;6's;10's;12's; As per DRAP's pricing Policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Zidor Capsule 250mg of M/s Winthrox Karachi . (Reg.# 074943)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16th – 28th August, 2018, concluding as under: "The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and

		progressive towards good level of GMP compliance."
	Remarks of the Evaluator[II]	
	Decision:Approved.	
43.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name +Dosage Form + Strength	Azibar 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…250mg"
	Diary No. Date of R& I & fee	Dy. No 11150 dated 27-03-2018 Rs.20,000/- 27-03-2018
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	4's,;6's;10's; As per DRAP's pricing Policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Azitma 250mg Tablet of M/s Sami Karachi. (Reg.# 074899)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
44.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name +Dosage Form + Strength	Azibar 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…500mg"
	Diary No. Date of R& I & fee	Dy. No 11150 dated 27-03-2018 Rs.20,000/- 27-03-2018
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2's;3's;6's;10's; As per DRAP's pricing Policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Azitma 500mg Tablet of M/s Sami Karachi. (Reg.# 074900)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
45.	Name and address of manufacturer / Applicant	"M/s Barrett Hodgson Pakistan Pvt Ltd. F/423, SITE, Karachi"
	Brand Name +Dosage Form + Strength	Azibar 200mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Azithromycin Dihydrate Eq. to Azithromycin…200mg"
	Diary No. Date of R& I & fee	Dy. No 11149 dated 27-03-2018 Rs.20,000/- 27-03-2018
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	15ml, 22.5ml,25ml,30ml; As per DRAP's pricing Policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Azitma 200mg/5ml dry suspension Tablet of M/s Sami Karachi. (Reg.# 074902)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	

46.	Name and address of manufacturer / Applicant	"M/s CherWel Pharmaceuticals Pvt Ltd. Plot # 20, Phase 4, Hattar Industrial Estate, Hattar, Kpk"
	Brand Name +Dosage Form + Strength	Welfine 250mg Tablet
	Composition	"Each film coated Tablet Contains: Terbinafine HCl …250mg"
	Diary No. Date of R& I & fee	Dy. No 10883 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Neoterbin Tablets 250mg by M/s Neomedix Pharmaceuticals, Islamabad. (Reg.# 081411)
	GMP status	Last GMP inspection was conducted on 4-2-2019 and panel recommend the renewal of DML
	Remarks of the Evaluator[II]	• In contrary to approved by the reference agencies/authorities wherein the applied formulation is approved as Terbinafine "as hydrochloride" equal to Terbinafine 250mg, while firm has applied for Terbinafine hydrochloride equal to 250mg. Clarification is required in this regard.
	Decision: Deferred for submission of composition as per reference product.	
47.	Name and address of manufacturer / Applicant	"M/s CherWel Pharmaceuticals Pvt Ltd. Plot # 20, Phase 4, Hattar Industrial Estate, Hattar, Kpk"
	Brand Name +Dosage Form + Strength	Moncher 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Montelukast as sodium …10mg"
	Diary No. Date of R& I & fee	Dy. No 10884 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Montekast 10mg Tablets of M/s Global Pharmaceuticals. (Reg.# 032154)
	GMP status	Last GMP inspection was conducted on 4-2-2019 and panel recommend the renewal of DML
	Remarks of the Evaluator[II]	
	Decision:Approved.	
48.	Name and address of manufacturer / Applicant	"M/s CherWel Pharmaceuticals Pvt Ltd. Plot # 20, Phase 4, Hattar Industrial Estate, Hattar, Kpk"
	Brand Name +Dosage Form + Strength	Domwel 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Domperidone Maleate Eq. to Domperidone…10mg"
	Diary No. Date of R& I & fee	Dy. No 10881 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Kohidone 10mg Tablet of M/s Kohs Pharmaceuticals (Pvt) Ltd. (Reg.# 070705)
	GMP status	Last GMP inspection was conducted on 4-2-2019 and panel

		recommend the renewal of DML
	Remarks of the Evaluator[II]	
	Decision:Approved.	
49.	Name and address of manufacturer / Applicant	"M/s CherWel Pharmaceuticals Pvt Ltd. Plot # 20, Phase 4, Hattar Industrial Estate, Hattar, Kpk"
	Brand Name +Dosage Form + Strength	C-Moxit 400mg Tablet
	Composition	Each Film Coated Tablet Contains: Moxifloxacin as hydrochloride……400mg
	Diary No. Date of R& I & fee	Dy.No 10882 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Swismox 400mg Tablet of M/s Swiss Pharma, Karachi. (Reg.# 070659)
	GMP status	Last GMP inspection was conducted on 4-2-2019 and panel recommend the renewal of DML
	Remarks of the Evaluator[II]	
	Decision:Approved.	
50.	Name and address of manufacturer / Applicant	"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"
	Brand Name +Dosage Form + Strength	Cardazin XR 500mg Tablets
	Composition	"Each Extended Release Film Coated Tablet Contains: Ranolazine…500mg"
	Diary No. Date of R& I & fee	Dy. No 10885 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Anti-anginal
	Type of Form	Form-5
	Finished product Specifications	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 (with strength and dosage form)	Ranola Tablets 500mg of M/s. Highnoon Laboratories (Reg.# 069039)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 24-01-2018, concluding as under: "Overall the firm was found to be operating at a very good level of cGMP Compliance at the time of inspection"
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
51.	Name and address of manufacturer / Applicant	"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"
	Brand Name +Dosage Form + Strength	Cardazin XR 1000mg Tablets
	Composition	"Each Extended Release Film Coated Tablet Contains: Ranolazine…….1000mg"
	Diary No. Date of R& I & fee	Dy. No 10886 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Anti-anginal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Ranola Tablets 1000mg of M/s. Highnoon Laboratories (Reg.# 069038)

	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
52.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No.11, Sector 12-A, North Karachi, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Semorfen 200mg/5ml DS Suspension
	Composition	"Each 5ml Contains: Ibuprofen……200mg"
	Diary No. Date of R& I & fee	Dy. No 11154 dated 27-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Brufen Suspension DS of M/s Abbott Karachi (Reg.# 070851)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-07-2018, Good GMP compliance level.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
53.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No.11, Sector 12-A, North Karachi, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Semorfen 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ibuprofen…….200mg"
	Diary No. Date of R& I & fee	Dy. No 11169 dated 27-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Hedex Ibuprofen Tablets of M/s Omega Pharma Ltd. approved by MHRA of UK
	Me-too status (with strength and dosage form)	Suprofen Tablet 200mg of M/s Kohs Hyderabad (Reg.# 070618)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-07-2018, Good GMP compliance level.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
54.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No.11, Sector 12-A, North Karachi, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Semorfen 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ibuprofen…….400mg"
	Diary No. Date of R& I & fee	Dy. No 11168 dated 27-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Ibuprofen Tablets 400mg of M/s Accord Healthcare Ltd. approved by MHRA of UK
	Me-too status (with strength and dosage form)	Suprofen Tablet 400mg of M/s Kohs Hyderabad (Reg.# 070619)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-07-2018, Good GMP compliance level.

	Remarks of the Evaluator[II]	
	Decision:Approved.	
55.	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	Laderfex 120mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine hydrochloride …… 120mg"
	Diary No. Date of R& I & fee	Dy. No 10442 dated 21-03-2018 Rs.20,000/- 20-03-2018
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Fanoxin Tablets 120mg. of M/s Jawa Pharmaceutical (Pvt) Ltd (Reg.# 052778)
	GMP status	The firm was last inspected on 29-01-2019, concluding that firm is overall GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with change of brand name.	
56.	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	Laderfex 180mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine hydrochloride …… 180mg"
	Diary No. Date of R& I & fee	Dy. No 10443 dated 21-03-2018 Rs.20,000/- 20-03-2018
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Fexokure Tablets 180mg. of M/s English Pharm (Reg.# 052411)
	GMP status	The firm was last inspected on 29-01-2019, concluding that firm is overall GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with change of brand name.	
57.	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	Laderfex 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine hydrochloride.….60mg"
	Diary No. Date of R& I & fee	Dy. No 10441 dated 21-03-2018 Rs.20,000/- 20-03-2018
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Fanoxin Tablets 60mg. of M/s Jawa Pharmaceutical (Pvt) Ltd (Reg.# 052779)
	GMP status	The firm was last inspected on 29-01-2019, concluding that firm is overall GMP compliant.

	Remarks of the Evaluator[II]	
	Decision: Approved with change of brand name.	
58.	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	Dentisept 0.15% w/v Mouthwash
	Composition	Each ml Contains: Benzydamine Hydrochloride…0.15% w/v
	Diary No. Date of R& I & fee	Dy. No 10439 dated 21-03-2018 Rs.20,000/- 20-03-2018
	Pharmacological Group	NSAID/Analgesic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Niflam Mouth Wash of M/s Platinum Pharmaceuticals (Pvt.) Ltd. (Reg.# 024874)
	GMP status	The firm was last inspected on 29-01-2019, concluding that firm is overall GMP compliant.
	Remarks of the Evaluator[II]	
	Decision:Approved with change of brand name.	
59.	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	Dentisept-C Mouthwash
	Composition	Each ml Contains: Benzydamine Hydrochloride…0.15% w/v Chlorhexidine Gluconate…0.12% w/v
	Diary No. Date of R& I & fee	Dy. No 10439 dated 21-03-2018 Rs.20,000/- 20-03-2018
	Pharmacological Group	NSAID/Antiseptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	DIFFLAM-C SORE THROAT GARGLE & MOUTH SOLUTION + ANTISEPTIC solution approved by TGA of Australia
	Me-too status (with strength and dosage form)	Benzaflam Solution of M/s Platinum Pharmaceuticals (Pvt.) Ltd. (Reg.# 048428)
	GMP status	The firm was last inspected on 29-01-2019, concluding that firm is overall GMP compliant.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification and with change of brand name	
60.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Hilomet 850mg Tablets
	Composition	"Each Film Coated Tablet Contains: Metformin hydrochloride …….850mg"
	Diary No. Date of R& I & fee	Dy. No 10454 dated 21-03-2018 Rs.20,000/- 21-03-2018
	Pharmacological Group	Anti-hyperglycemic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's;30's;50's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Glumet 850mg Tablet of M/s Swiss Pharma Karachi (Reg.# 076070)
	GMP status	GMP Certificate issued on 19-02-2018.

	Remarks of the Evaluator[II]	
	Decision:Approved.	
61.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Hilomet 500mg Tablets
	Composition	"Each Film Coated Tablet Contains: Metformin hydrochloride …….500mg"
	Diary No. Date of R& I & fee	Dy. No 10453 dated 21-03-2018 Rs.20,000/- 21-03-2018
	Pharmacological Group	Anti-hyperglycemic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's;30's;50's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Glucotech 500mg Tablet of M/s Uni-Tiech Pharmaceuticals, Karachi (Reg.# 061038)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
62.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Hilomet 1000mg Tablets
	Composition	"Each Film Coated Tablet Contains: Metformin hydrochloride …….1000mg"
	Diary No. Date of R& I & fee	Dy. No 10456 dated 21-03-2018 Rs.20,000/- 21-03-2018
	Pharmacological Group	Anti-hyperglycemic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's;30's;50's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Glumet 1gm Tablet of M/s Swiss Pharma Karachi (Reg.# 076071)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
63.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Hilomet 250mg Tablets
	Composition	"Each Film Coated Tablet Contains: Metformin hydrochloride …….250mg"
	Diary No. Date of R& I & fee	Dy. No 10452 dated 21-03-2018 Rs.20,000/- 21-03-2018
	Pharmacological Group	Anti-hyperglycemic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100's;30's;50's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Glucotech 250mg Tablet of M/s Uni-Tiech Pharmaceuticals, Karachi (Reg.# 061037)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

64.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citihil 1000mg/4ml Injection
	Composition	"Each ml solution for Injection Contains: Citicoline as Sodium…250mg"
	Diary No. Date of R& I & fee	Dy. No 11714 dated 30-03-2018 Rs.20,000/- 29-03-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	4ml ampoule; 1's;10's;5's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Citicolina Ferrer 1000 Mg Solucion Inyectable of M/s Ferrer Internacional, S.A. approved by AEMPS of Spain. (https://cima.aemps.es/cima/publico/detalle.html)
	Me-too status (with strength and dosage form)	Citolin 4ml Injection of M/s Global Pharmaceuticals (Reg.# 030541)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
65.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citihil 100mg/2ml Injection
	Composition	Each ml solution for Injection Contains: Citicoline as Sodium……50mg
	Diary No. Date of R& I & fee	Dy. No 11711 dated 30-03-2018 Rs.20,000/- 29-03-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2ml ampoule; 1's;10's;5's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status (with strength and dosage form)	Not verifiable
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision:Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
66.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citihil 500mg/5ml Oral Solution
	Composition	Each 5ml solution Contains: Citicoline as Sodium…500mg
	Diary No. Date of R& I & fee	Dy. No 11710 dated 30-03-2018 Rs.20,000/- 29-03-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml,120ml glass bottle; as per DPC

	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain.
	Me-too status (with strength and dosage form)	Cercolin Syrup of M/s Schazoo Laboratories (Reg.# 048985)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
67.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citihil 500mg/4ml Injection
	Composition	Each ml solution for Injection Contains: Citicoline as Sodium…125mg
	Diary No. Date of R& I & fee	Dy. No 11713 dated 30-03-2018 Rs.20,000/- 29-03-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	4ml ampoule; 1's;10's;5's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	Medicoline injection by M/s Mediceena Pharma (Reg.# 047790)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
68.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citihil 250mg/2ml Injection
	Composition	Each ml solution for Injection Contains: Citicoline as Sodium…125mg
	Diary No. Date of R& I & fee	Dy. No 11712 dated 30-03-2018 Rs.20,000/- 29-03-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2ml ampoule; 1's;10's;5's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	Coline Injection of M/s Neutro (Reg.#038828)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
69.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citihil 500mg Tablets
	Composition	"Each Film Coated Tablet Contains: Citicoline as Sodium…500mg"
	Diary No. Date of R& I & fee	Dy. No 11709 dated 30-03-2018 Rs.20,000/- 29-03-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's;20's;30's; as per DPC
	Approval status of product in Reference Regulatory Authorities	Not verifiable

	Me-too status (with strength and dosage form)	Cercolin Tablets of M/s Schazoo Laboratories (Reg.#048984)
	GMP status	GMP Certificate issued on 19-02-2018.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
70.	Name and address of manufacturer / Applicant	"M/s Pearl Pharmaceuticals. Plot No. 204, Street No.1, I-10/3, Islamabad"
	Brand Name +Dosage Form + Strength	Futisone Lotion
	Composition	"Each 20ml Bottle Contains: Fluticasone Propionate…0.05% w/v"
	Diary No. Date of R& I & fee	Dy. No 10670 dated 22-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Aproved by USFDA
	Me-too status (with strength and dosage form)	Ticovate Lotion of Saffron Pharma (Reg# 067826)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 19-02-2017, recommending grant of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision: Approved with USP specifications.	
71.	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	Pimporin 1g Injection
	Composition	"Each Vial Contains: Cefepime HCL and Arginine Eq. to Cefepime…1gm"
	Diary No. Date of R& I & fee	Dy. No 10666 dated 22-03-2018 Rs. 20,000/- 16-03-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nuxipim 1g Injection of Bosch
	GMP status	GMP certificate valid till 07-05-2019
	Remarks of the Evaluator[II]	
	Decision:Approved.	
72.	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	Pimporin 2g Injection
	Composition	"Each Vial Contains: Cefepime HCL and Arginine Eq. to Cefepime…2gm"
	Diary No. Date of R& I & fee	Dy.No 10667 dated 22-03-2018 Rs. 20,000/- 16-03-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	Feldopim 2 g Injection of M/s Wnsfeild Pharmaceutical, (Reg.#075600)
	GMP status	GMP certificate valid till 07-05-2019
	Remarks of the Evaluator[II]	
	Decision:Approved.	
73.	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	Pimporin 500mg Injection
	Composition	"Each Vial Contains: Cefepime HCl and Arginine Eq. to Cefepime…500mg"
	Diary No. Date of R& I & fee	Dy. No 10665 dated 22-03-2018 Rs. 20,000/- 16-03-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Feldopim 500mg Injection of M/s Wnsfeild Pharmaceutical, (Reg.#046970)
	GMP status	GMP certificate valid till 07-05-2019
	Remarks of the Evaluator[II]	
	Decision: Approved	
74.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Lowstatin 20mg Tablets
	Composition	"Each film coated Tablet Contains: Rosuvastatin as calcium……20mg"
	Diary No. Date of R& I & fee	Dy. No 11767 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 300/-
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Rosunext Tablets 20mg by M/s Novamed Pharma. (Reg.# 064848)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 14-02-2018, concluding as under: Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Trigon Pharmaceuticals Pvt. Ltd Lahore was considered to be operating at Satisfactory level of compliance with CGMPguidelines as per DRUGS ACT, 1976 and rules framed there under at the time of inspection. **Recommendations:** The observation of the Inspection as highlighted in ***bold italic font*** were discus with management at length. The management expressed very firm commitment for earlier compliance to the suggestions for further approving of GMP"
	Remarks of the Evaluator[II]	• In contrary to reference product, which is available as film coated tablet, you have applied for film uncoated tablet. • Salt form of API is not mentioned in Form-5. • Upon communication of above observation firm has submitted revised Form-5 for film coated tablets along with fee of Rs. 5,000/- for revision of formulation vide

		deposit slip# 1911514 dated 08-05-2019.
	Decision: Approved.	
75.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Domwel 10mg Tablet	Teragon 2mg Tablet
	Composition	"Each Tablet Contains: Terazosin as hydrochloride dihydrate …… 2mg"
	Diary No. Date of R& I & fee	Dy. No 11768 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's; Rs. 500/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Hyzosin Tablet 2mg by M/s English Pharm. (Reg.# 068007)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	In contrary to reference product approved by MHRA of UK, which is available as uncoated tablet, you have applied for film coated tablet. Upon communication of above observation firm has submitted revised Form-5 for uncoated tablets along with fee of Rs. 5,000/- for revision of formulation vide deposit slip# 1911517 dated 08-05-2019.
	Decision: Approved.	
76.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Teragon 5mg Tablet
	Composition	"Each Tablet Contains: Terazocin as hydrochloride …… 5mg"
	Diary No. Date of R& I & fee	Dy. No 11769 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's; Rs. 1200/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Hyzosin Tablet 5mg by M/s English Pharm. (Reg.# 068003)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	In contrary to reference product approved by MHRA of UK, which is available as uncoated tablet, you have applied for film coated tablet. Upon communication of above observation firm has submitted revised Form-5 for uncoated tablets along with fee of Rs. 5,000/- for revision of formulation vide deposit slip# 1911515 dated 08-05-2019.
	Decision: Approved.	
77.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Azigon 250mg Tablet
	Composition	"Each film coated tablet contains: Azithromycin as dihydrate ……. 250mg"
	Diary No. Date of R& I & fee	Dy. No 11737 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 210/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Prizocin Tablets 250 mg by M/s Nimrall Pharmaceuticals. (Reg.# 066683)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
78.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Pepgon 40mg Tablet
	Composition	"Each enteric coated tablet Contains: Esomeprazole as magnesium trihydrate…..… 40mg"
	Diary No. Date of R& I & fee	Dy. No 11739 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's; Rs. 170/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Esoton-40mg Tablet by M/s Hygeia Pharmaceuticals, Islamabad. (Reg.# 081204)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	Firm has submitted Rs. 5,000/- fee vide deposit slip# 1911518 dated 08-05-2019 for revision of formulation, since salt form of API was not previously mentioned.
	Decision: Approved with innovator's specifications.	
79.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Risgon 1mg Tablets
	Composition	"Each film coated Tablet Contains: Risperidone ……1mg"
	Diary No. Date of R& I & fee	Dy. No 11746 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 80/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tablet Resjun -1 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081921)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
80.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Risgon 2mg Tablet
	Composition	"Each film coated Tablet Contains: Risperidone ……2mg"
	Diary No. Date of R& I & fee	Dy. No 11746 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 200/-

	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tablet Resjun -2 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081922)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
81.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Risgon 3mg Tablet
	Composition	"Each film coated Tablet Contains: Risperidone ……3mg"
	Diary No. Date of R& I & fee	Dy. No 11748 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 200/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Becalm 3mg Tablet of M/s Maple Pharmaceuticals, Karachi (Reg.# 058206)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
82.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trimantin 10mg Tablet
	Composition	"Each film coated tablet Contains: Memantine as hydrochloride…….10mg"
	Diary No. Date of R& I & fee	Dy. No 11765 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14's; Rs. 470/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Namentec 10mg Tablet of M/s Pharmatech Karachi (Reg.# 075937)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
83.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trilepsi 250mg Tablet
	Composition	"Each film coated tablet Contains: Levetiracetam…….250mg"
	Diary No. Date of R& I & fee	Dy. No 11742 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Second generation antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 190/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Keppra Tablets 250mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045684)

	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
84.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Triamloval 5/80 mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate ….. 5mg Valsartan ……. 80mg "
	Diary No. Date of R& I & fee	Dy. No 11758 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Calcium channel blocker/Angiotensin-II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's; Rs. 120/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Exforge Tablet of M/s Novartis Pharma (Reg.#047569)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
85.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Triamloval 10/160 mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate ……10mg Valsartan …….160mg"
	Diary No. Date of R& I & fee	Dy. No 11759 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Calcium channel blocker/Angiotensin-II receptor blocker
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's; Rs. 760/-
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength & dosage form)	Co-Valzaar 10mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
86.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trigem 320mg Tablet
	Composition	"Each film coated Tablet Contains: Gemifloxacin as mesylate ……320mg"
	Diary No. Date of R& I & fee	Dy. No 11740 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1 x 7's; Rs. 900/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Gatiking 320 mg tablets of M/s Welwrd Pharmaceuticals (Reg.# 078481)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	

87.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trilepsi 500mg/5ml Injection
	Composition	"Each ml Contains: Levetiracetam ……100mg"
	Diary No. Date of R& I & fee	Dy. No 11741 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	5ml ampoule x 1's; Rs. 315/-
	Approval status of product in Reference Regulatory Authorities	Desitrend 100 mg/ml concentrate for solution for infusion of M/s Desitin Pharma Ltd. approved by MHRA of UK. (https://www.medicines.org.uk/emc/product/7345/smpc)
	Me-too status (with strength and dosage form)	Eplipsa 500mg/5ml Injection of M/s Helix Karachi (Reg.#075918)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	
88.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Ttrifer 50mg/ml Injection
	Composition	"Each ml Contains: Iron (III) isomaltoside 1000 eq. to elemental Iron …… 50mg
	Diary No. Date of R& I & fee	Dy. No 11764 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Iron parenteral preparation
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	2ml ampoule x 5's; Rs. 2700/-
	Approval status of product in Reference Regulatory Authorities	Diafer 50 mg/ml solution for injection of Pharmacosmos UK Limited. approved by MHRA of UK. (https://www.medicines.org.uk/emc/product/5324/smpc)
	Me-too status (with strength and dosage form)	Not available.
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• Evidence of applied formulation/drug in the applied fill volume of 2ml, 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 in the applied fill volume of 2ml, already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
89.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals (Pvt) Limited, 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Piroxigon-B 20mg Tablet
	Composition	"Each Tablet Contains: Piroxicam β-Cyclodextrin …… 20mg "
	Diary No. Date of R& I & fee	Dy. No 11745 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's; Rs. 160/-
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (with strength and dosage form)	Achway Tablets of M/s Getz Pharma (Reg.#047355)

	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
90.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trilepsi 750mg Tablet
	Composition	"Each film coated Tablet Contains: Levetiracetam……750mg"
	Diary No. Date of R& I & fee	Dy. No 11744 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 570/-
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (with strength and dosage form)	Saveta 750mg Tablets of Getz Pharma Karachi. (Reg.# 081079)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
91.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dexifen 400mg Tablet
	Composition	"Each film coated Tablet Contains: Dexibuprofen……400mg"
	Diary No. Date of R& I & fee	Dy. No 11762 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	3 x 10's; Rs. 300/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dexwel Tablets of M/s Welwrd Pharmaceutical. (Reg.#076813)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator' sspecifications.	
92.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trixetine 20mg Tablet
	Composition	"Each film coated Tablet Contains: Paroxetine as hydrochloride……..20mg"
	Diary No. Date of R& I & fee	Dy. No 11766 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's; Rs. 380/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Paroxiwel 20 mg Tablets of M/s Welwrd Pharmaceutical. (Reg.#075517)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	

93.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Clozagon 25mg Tablet
	Composition	"Each Tablet contains: Clozapine……25mg"
	Diary No. Date of R& I & fee	Dy. No 11760 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-psychotics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5 x 10's; Rs.780/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Clogen Tablets 25 mg of M/s Genera Pharmaceuticals. (Reg.#069989)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
94.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Azigon 500mg Tablet
	Composition	"Each film coated tablet contains: Azithromycin as dihydrate……500mg"
	Diary No. Date of R& I & fee	Dy. No 11738 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs.410/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Azitma 500mg Tablet of M/s Sami Karachi. (Reg.# 074900)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
95.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Olan-T 3/25 mg Tablet
	Composition	"Each film coated tablet contains: Olanzapine.....…....3mg Fluoxetine….....25mg
	Diary No. Date of R& I & fee	Dy. No 11752 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antipsychotic /Antidepressants in combination with psycholeptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14's; Rs.200/-
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status (with strength and dosage form)	NA
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved

		by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
96.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Tristron 8mg Tablet
	Composition	"Each film coated tablet Contains: Ondansetron as hydrochloride dihydrate …… 8mg"
	Diary No. Date of R& I & fee	Dy. No 11751 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-emetics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs.3695/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Ondonx Tablet of M/s Genix Pharma Karachi (Reg.#081451)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
97.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Apo-lowclot 75mg Tablet
	Composition	Each film coated Tablet Contains: Clopidogrel as bisulphite …….75mg Aspirin…….....75mg
	Diary No. Date of R& I & fee	Dy. No 11750 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-emetics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs.130/-
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	CoPlavix Tablets 75/75mg of M/s Sanofi Karachi. (Reg.#075978)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Deferred for verification of innovator's product either plain or bi-layered tablet.	
98.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Daylong 10mg Tablet
	Composition	"Each film coated Tablet Contains: Cetrizine hydrochloride…10mg"
	Diary No. Date of R& I & fee	Dy. No 11749 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 x 10's; Rs.350/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage	Serzine 10mg Tablets of M/s Qintar Pharmaceuticals, 14-A

	form)	S.I.E Lahore Road, Sargodha. (Reg.# 030644)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved with change of brand name.	
99.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Clozagon 100mg Tablet
	Composition	"Each Tablet Contains: Clozapine…100mg"
	Diary No. Date of R& I & fee	Dy. No 11761 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-psychotics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5 x 10's; Rs.1700/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Clogen Tablets 100 mg of M/s Genera Pharmaceuticals. (Reg.#069990)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
100.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Triamloplus 5/10 mg Tablet
	Composition	"Each film coated tablet contains: Amlodipine as besylate…5mg Atorvastatan as calcium……10mg"
	Diary No. Date of R& I & fee	Dy. No 11761 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 7's; Rs.120/-
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Caprisk Tablets 5/10mg of M/s. Wilshire Laboratories (Pvt) Ltd (Reg.#065670)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
101.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Triopram 10mg Tablet
	Composition	"Each film coated Tablet Contains: Escitalopram as Oxalate……10mg"
	Diary No. Date of R& I & fee	Dy. No 11755 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs.150/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength & dosage form)	Zavesca tablet 10mg of Getz Pharma. (Reg.#045279)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	

	Decision: Approved.	
102.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Anxietoline 50mg Tablet
	Composition	"Each film coated Tablet Contains: Sertraline as hydrochloride…….50mg"
	Diary No. Date of R& I & fee	Dy. No 11754 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	SSRI
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's; Rs.1550/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Yesme Tablet 50mg by M/s Metro Pharmaceuticals, Islamabad. (Reg.#081674)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved with change of brand name	
103.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Triamloplus 10/20 mg Tablet
	Composition	"Each film coated tablet contains: Amlodipine as besylate ….. 10mg Atorvastatin as calcium ……20mg"
	Diary No. Date of R& I & fee	Dy. No 11757 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 14's; Rs.290/-
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Caprisk Tablet 10/20mg of M/s. Wilshire Laboratories (Pvt) Ltd (Reg.#067734)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
104.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Trilepsi 500mg Tablet
	Composition	"Each film coated tablet Contains: Levetiracetam…….500mg"
	Diary No. Date of R& I & fee	Dy. No 11743 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Second generation antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 350/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Keppra Tablets 500mg by M/s AGP (Pvt.) Ltd, Karachi (Reg. No. 045685)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	

105.	Name and address of manufacturer / Applicant	"M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Lopgon 50/12.5 mg Tablet
	Composition	"Each film coated tablet Contains: Losartan potassium…50mg Hydrochlorothiazide……12.5mg"
	Diary No. Date of R& I & fee	Dy. No 11753 dated 30-03-2018 Rs.20,000/- 30-03-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	2 x 10's; Rs. 280/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Invase-H 50mg+12.5mg Tablets by M/s Sami Pharmaceutical, Karachi (Reg. No. 044274)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
106.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacivan-T 20/25 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…….20mg Hydrochlorothiazide……..25mg"
	Diary No. Date of R& I & fee	Dy. No 10919 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	1 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Olmetab –H tablets by M/s Wilson's Pharma (Reg.#077725)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 22/02/2018, concluding good level of GMP compliance at the time of inspection
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
107.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacivan-T 40/12.5 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy. No 10916 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	1 x 10's, 2 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Olmetab –H tablets by M/s Wilson's Pharmaceuticals, (Reg. No. 077723)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	

108.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacigab 150mg Capsules
	Composition	"Each Hard Gelatin Capsule Contains: Pregabalin…150mg"
	Diary No. Date of R& I & fee	Dy. No 10943 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 7's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 150mg Capsule by M/s Getz Pharma (Reg#048724)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
109.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacigab 300mg Capsules
	Composition	"Each Hard Gelatin Capsule Contains: Pregabalin…300mg"
	Diary No. Date of R& I & fee	Dy. No 10944 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 7's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 300mg Capsule by M/s Getz Pharma (Reg#047368)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
110.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacigab 100mg Capsules
	Composition	"Each Hard Gelatin Capsule Contains: Pregabalin…100mg"
	Diary No. Date of R& I & fee	Dy. No 10942 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 7's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
111.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacigab 50mg Capsules
	Composition	"Each Hard Gelatin Capsule Contains: Pregabalin.....…50mg"

	Diary No. Date of R& I & fee	Dy. No 10940 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 7's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 50mg Capsules by M/s Getz Pharma, Karachi (Reg. No. 048725)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
112.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacivan-A 20/5 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg Amlodipine as Besylate…5mg"
	Diary No. Date of R& I & fee	Dy. No 10918 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 10's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Baritec-A 20/5mg Tablet by M/s Barret Hodgson, Karachi (Reg. No. 081442)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
113.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacivan-A 40/5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Amlodipine Besylate…5mg"
	Diary No. Date of R& I & fee	Dy. No 10921 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 10's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Baritec-A 40/5mg Tablet by M/s Barret Hodgson, Karachi (Reg. No. 081443)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
114.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Trama 50mg Capsules
	Composition	"Each Capsule Contains: Tramadol hydrochloride…50mg"
	Diary No. Date of R& I & fee	Dy. No 10922 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Opiate analogue

	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1 x 10's, 2 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Tramadol 50mg capsule by Milpharm Ltd, approved by MHRA of UK.
	Me-too status (with strength and dosage form)	Tramal capsule 50mg by Impex Plus Karachi (Reg#010170)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
115.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Tizaxidine 2mg Tablets
	Composition	"Each Tablet Contains: Tizanidine as hydrochloride……2mg"
	Diary No. Date of R& I & fee	Dy.No 10936 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Centrally acting agent; muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Xinasia Tablets by Med Asia Pharmaceuticals (Pvt) Ltd. (Reg#078514)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• In contrary to reference product which is approved as Tizanidine hydrochloride equivalent to Tizanidine 2mg, firm had initially applied for Tizanidine equal to 2mg. • Upon communication of above observation firm has submitted revised Form-5 with composition as per reference product, with submission of fee of Rs. 5,000/- vide deposit slip# 1916162 dated 25-03-2019 for change of formulation.
	Decision:Approved.	
116.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacigab 75mg Capsules
	Composition	"Each Hard Gelatin Capsule Contains: Pregabalin…75mg"
	Diary No. Date of R& I & fee	Dy. No 10941 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	2 x 7's;As per the brand leader
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Gabica by M/s Getz Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
117.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Trama 100mg Capsule
	Composition	"Each extended release capsule contains:

		Tramadol hydrochloride…100mg"
	Diary No. Date of R& I & fee	Dy. No 10922 dated 26-03-2018 Rs. 20,000/- Dated 21-03-2018
	Pharmacological Group	Opiate analogue
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	1 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Conzip capsules approved by USFDA as Extended release capsules
	Me-too status (with strength and dosage form)	Zultra SR 100mg by M/s. Wilshire Laboratories (Pvt.) Ltd; (Reg#080714)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• In contrary to reference product approved by USFDA, which is available as extended release capsule, firm had initially applied for immediate release capsules. Clarification shall be submitted in this regard. • Upon communication of above observation firm has submitted revised Form-5 with composition as per reference product, with submission of fee of Rs. 5,000/- vide deposit slip# 1916163 dated 25-03-2019 for change of formulation.
	Decision:Approved.	
118.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Phenadrin-P Tablets
	Composition	"Each Tablet Contains: Orphenadrine citrate…35mg Paracetamol…….450mg"
	Diary No. Date of R& I & fee	Dy. No 10928 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Narcotic analgesic combination
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications.
	Pack size & Demanded Price	1 x 10's, 2 x 10's, 2 x 12's, 3 x 10's, 5 x 10's, 10 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Norgesic of M/s iNova Pharmaceuticals Australia Pvt. Ltd approved by TGA of Australia
	Me-too status (with strength and dosage form)	Rid-All Forte by M/s Stanley Pharma (Reg.#069786)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
119.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacivan 20mg Tablets
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg"
	Diary No. Date of R& I & fee	Dy. No 10917 dated 26-03-2018 Rs. 20,000/- Dated 21-03-2018
	Pharmacological Group	Angiotensin-II antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's, 2 x 7's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Olmeday tablets 20mg by M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad (Reg.#075378)

	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
120.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Pacivan 40mg Tablets
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg"
	Diary No. Date of R& I & fee	Dy. No 10920 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Angiotensin-II antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's, 2 x 7's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Olmeday tablets 40mg by M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad (Reg.#075379)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
121.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Tizaxidine 4mg Tablets
	Composition	"Each Tablet Contains: Tizanidine as hydrochloride…4mg"
	Diary No. Date of R& I & fee	Dy.No 10945 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Centrally acting agent; muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SN Skelax 4 mg Tablets by M/s SNB Pharma (Pvt) Ltd. (Reg#078413)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• In contrary to reference product which is approved as Tizanidine hydrochloride equivalent to Tizanidine 4mg, firm had initially applied for Tizanidine equal to 4mg. • Upon communication of above observation firm has submitted revised Form-5 with composition as per reference product, with submission of fee of Rs. 5,000/- vide deposit slip# 1916161 dated 25-03-2019 for change of formulation
	Decision:Approved.	
122.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Tamalgesic-P Tablets
	Composition	"Each film Coated Tablet Contains: Tramadol hydrochloride…37.5mg Paracetamol…325mg"
	Diary No. Date of R& I & fee	Dy. No 10924 dated 26-03-2018 Rs. 20,000/- 21-03-2018
	Pharmacological Group	Analgesic/ Opioid Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's, 2 x 10's; As per the brand leader

	Approval status of product in Reference Regulatory Authorities	Ultracet by Janssen (USFDA)
	Me-too status (with strength and dosage form)	Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
123.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Imizine 25mg Tablets
	Composition	"Each Sugar Coated Tablet Contains: Imipramine…25mg"
	Diary No. Date of R& I & fee	Dy. No 10933 dated 26-03-2018 Rs. 20,000/- 22-03-2018
	Pharmacological Group	Non selective monoamine reuptake inhibitor
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	20 x 10's; As per the brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Imral 25mg Tablets by Sayyed Pharmaceuticals (Pvt) Ltd (Reg. No. 070379)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
124.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Thiosim 4mg Tablet
	Composition	"Each Tablet Contains: Thiocolchicoside…….4mg"
	Diary No. Date of R& I & fee	Dy. No 10668 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France.
	Me-too status (with strength and dosage form)	Wodnik 4mg Tablet of M/s Martin Dow (Reg.# 081138)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10-04-2018, concluding an acceptable level of compliance with good manufacturing practices for Pharma products
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	
125.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Thiosim 4mg Capsule
	Composition	"Each Capsule Contains: Thiocolchicoside…4mg"
	Diary No. Date of R& I & fee	Dy. No 10669 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Muscle relaxant
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Myoplege 4 mg capsule by Laboratories GENEVRIER SA (ANSM approved)

	Me-too status (with strength and dosage form)	Muscor 4mg Capsule by M/s Genome Pharmaceuticals Pvt. Ltd.(Reg#046466)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	No USP or BP monograph is available for applied formulation.
	Decision:Approved with innovator's specification.	
126.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Vomiz 10mg Tablet
	Composition	"Each film coated Tablet Contains: Domperidone……10mg"
	Diary No. Date of R& I & fee	Dy. No 10673 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Peripheral dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	5 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength and dosage form)	Epodom 10mg Tablets of M/s Atlantic Pharmaceutical (Pvt.) Ltd, (Reg.# 062326)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10-04-2018, concluding an acceptable level of compliance with good manufacturing practices for Pharma products
	Remarks of the Evaluator[II]	• In contrary to reference product approved by TGA of Australia which is available as film coated tablet, firm had initially applied for uncoated tablet. Upon communication of above observation firm has submitted revised formulation for film coated tablets, along with fee of Rs. 5,000 vide deposit slip# 0815680 dated 01-04-2019
	Decision:Approved with innovator's specification.	
127.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Vomiz-V 12.72mg Tablet
	Composition	"Each Tablet Contains: Domperidone Maleate……12.72mg"
	Diary No. Date of R& I & fee	Dy. No 10674 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Peripheral dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	5 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Motilium 10mg tablet of M/s Janssen-Cilag
	GMP status	GMP certificate issued on 26-01-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
128.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot# 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Acuvis 37.5/325 mg Tablets
	Composition	"Each film coated Tablet Contains: Tramadol hydrochloride…37.5mg Paracetamol…325mg"
	Diary No. Date of R& I & fee	Dy. No 10677 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Analgesic/ Opioid Analgesic
	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	Ultracet by Janssen (USFDA)
	Me-too status (with strength and dosage form)	Distalgesic Tablets by Atco laboratories, Karachi (R. No. 073865)
	GMP status	GMP certificate issued on 26-01-2018.
	Remarks of the Evaluator[II]	• In contrary to reference product which is available as film coated tablet, firm had initially applied for uncoated tablet. Clarification shall be submitted in this regard. • Upon communication of above observation firm has submitted revised formulation for film coated tablets, along with fee of Rs. 5,000 vide deposit slip# 0815679 dated 01-04-2019
	Decision:Approved.	
129.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Dimenate 50mg Tablet
	Composition	"Each Tablet Contains: Dimenhydrinate……50mg"
	Diary No. Date of R& I & fee	Dy. No 10676 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Antihistamine
	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	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mendate Tablets by Hicon Pharmaceuticals Peshawar (Reg. No. 077430)
	GMP status	GMP certificate issued on 26-01-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
130.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Examic 500mg/5ml Injection
	Composition	"Each 5ml ampoule Contains: Tranexamic acid…500mg"
	Diary No. Date of R& I & fee	Dy. No 10675 dated 22-03-2018 Rs.20,000/- 22-03-2018
	Pharmacological Group	Anti-Fibrinolytic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Cyklokapron 500mg Solution for Injection by M/s Pfizer Limited (MHRA approved)
	Me-too status (with strength and dosage form)	Traxacid Injection 500mg/5ml by M/s Asian Continental (Reg#057866)
	GMP status	GMP certificate issued on 26-01-2018.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
131.	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	Citap 100mg Tablet
	Composition	"Each film coated Tablet Contains: Sitagliptin as phosphate monohydrate…….100mg"
	Diary No. Date of R& I & fee	Dy. No 10877 dated 26-03-2018 Rs.20,000/- 26-03-2018

	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Gliptin Tablets of M/s Himont Pharma (Pvt.) Ltd, (Reg.# 076858)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 20-2-2018, concluding as under: "Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012."
	Remarks of the Evaluator[II]	
	Decision:Approved.	
132.	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	Omilok 40/1100 mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Omeprazole……40mg Sodium Bicarbonate…….1100mg"
	Diary No. Date of R& I & fee	Dy. No 10874 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Proton pump inhibitor/Antacid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Omsod 40 mg Capsules of M/s Reliance Pharma, (Reg.# 072154)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
133.	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	Omilok 20/1100 mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Omeprazole…20mg Sodium Bicarbonate…….1100mg"
	Diary No. Date of R& I & fee	Dy. No 10873 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Proton pump inhibitor/Antacid
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Omsod 20 mg Capsules of M/s Reliance Pharma, (Reg.# 072153)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
134.	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	Omilok 20/1680 mg Sachet

	Composition	"Each Sachet Contains: Omeprazole…20mg Sodium Bicarbonate…1680mg"
	Diary No. Date of R& I & fee	Dy. No 10876 dated 26-03-2018 Rs.50,000/- 26-03-2018
	Pharmacological Group	Proton pump inhibitor/Antacid
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	RISEK INSTA Powder by Getz Pharma (Pvt.) Ltd. (Reg.# 058547)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
135.	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	Omilok 40/1680 mg Sachet
	Composition	"Each Sachet Contains: Omeprazole…40mg Sodium Bicarbonate…1680mg"
	Diary No. Date of R& I & fee	Dy. No 10875 dated 26-03-2018 Rs.50,000/- 26-03-2018
	Pharmacological Group	Proton pump inhibitor/Antacid
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Ruling + Sachet by M/s High-Q, Karachi. (Reg.# 070633)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
136.	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	Urbifen 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Flurbirpofen……100mg"
	Diary No. Date of R& I & fee	Dy. No 10872 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada
	Me-too status (with strength and dosage form)	Strefen Tablets of Healers Pharmaceuticals (Reg.# 069733)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
137.	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	Urbifen 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Flurbirpofen……50mg"

	Diary No. Date of R& I & fee	Dy. No 10871 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada
	Me-too status (with strength and dosage form)	Floriwel 50mg Tablets of M/s Welmark Pharmaceuticals (Reg.# 064387)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
138.	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	Asomox 400mg Tablets
	Composition	"Each Film Coated Tablet Contains: Moxifloxacin Hydrochloride 436.37mg Eq. to Moxifloxacin……...400mg"
	Diary No. Date of R& I & fee	Dy. No 10867 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Metoxim 400mg Tablet by M/s Foray Pharmaceutical
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
139.	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	Citap-M 50/1000 mg Tablet
	Composition	"Each film coated tablet contains: Sitagliptin as phosphate monohydrate……50mg Metformin hydrochloride……1000mg"
	Diary No. Date of R& I & fee	Dy. No 10879 dated 26-03-2018 Rs.20,000/- 26-03-2018
	Pharmacological Group	Anti-diabetic agent and oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sitamet tablet by M/s CCL Pharmaceuticals Pvt. Ltd.
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
140.	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	Citap-M 50/500 mg Tablet
	Composition	"Each film coated tablet contains: Sitagliptin as phosphate monohydrate……50mg Metformin hydrochloride……500mg"
	Diary No. Date of R& I & fee	Dy. No 10878 dated 26-03-2018 Rs.20,000/- 26-03-2018

	Pharmacological Group	Anti-diabetic agent and oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sitamet tablet by M/s CCL Pharmaceuticals Pvt. Ltd.
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
141.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Molac 10mg/ml Injection
	Composition	"Each ml Contains: Ketorolac Tromethamine…….10mg"
	Diary No. Date of R& I & fee	Dy. No 11359 dated 28-03-2018 Rs.20,000/- 27-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1ml; As per latest DPC
	Approval status of product in Reference Regulatory Authorities	US-FDA Approved.
	Me-too status (with strength and dosage form)	Tromit Injection of Standpharm (Reg.# 049959)
	GMP status	GMP certificate issued on 23-05-2018
	Remarks of the Evaluator[II]	
	Decision:Approved.	
142.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Molac 30mg/ml Injection
	Composition	"Each ml Contains: Ketorolac Tromethamine…30mg"
	Diary No. Date of R& I & fee	Dy. No 11360 dated 28-03-2018 Rs.20,000/- 27-03-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1ml; As per latest DPC
	Approval status of product in Reference Regulatory Authorities	US-FDA Approved.
	Me-too status (with strength and dosage form)	Tromit Injection of Standpharm (Reg.# 049960)
	GMP status	GMP certificate issued on 23-05-2018
	Remarks of the Evaluator[II]	
	Decision:Approved.	
143.	Name and address of manufacturer / Applicant	"M/s Avant Pharmaceuticals (Pvt.) ltd., Karachi"
	Brand Name +Dosage Form + Strength	Paroxiwel 20mg tablet
	Composition	"Each film coated tablet contains: Paroxetine as hydrochloride hemihydrate…….20mg"
	Diary No. Date of R& I & fee	Dy. No 43820 dated 26-12-2018 (Duplicate dossier) Rs.20,000/- Dated 03-11-2017 (Photocopy)
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK.
	Me-too status (with strength and dosage form)	Neoxetine Tablets 20mg of M/s Neomedix Pharmaceuticals, Islamabad (Reg.# 081407)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 20-2-2018, concluding overall rating of GMP good at the time of inspection.
	Remarks of the Evaluator[II]	The firm has submitted duplicate dossier and as per record retrieved from R & I section forwarded by Reg-II section dated 01-03-2019 (attached with dossier) initial submission date of dossier has been verified as 09-11-2017 (Dy. No R&I 20499).
	Decision:Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
144.	Name and address of manufacturer / Applicant	"M/s Wellborne Pharmachem and Biologicals, Plot No.51/1 – 52/1, Phase-II, Industrial Estate, Hattar."
	Brand Name +Dosage Form + Strength	Salino 0.9% injection
	Composition	"Each 5ml contains: Sodium chloride…….45mg"
	Diary No. Date of R& I & fee	Dy. No R&I : 155 dated 16-06-2015 (Original dossier) Dy. No R&I : 32408 dated 28-09-2018 Rs.20,000/- Dated 16-06-2015 (Photocopy)
	Pharmacological Group	Electrolyte
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	USP
	Pack size & Demanded Price	5ml: As fixed by Government
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status (with strength and dosage form)	Sacro Injection of Macter Intr. Karachi. (Reg.# 079756)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 27-06-2018, concluding that firm is operating under good level of cGMP.
	Remarks of the Evaluator[II]	The firm has submitted duplicate dossier and as per record retrieved from R & I section forwarded by Reg-I section dated 04-03-2019 (attached with dossier) initial submission date of dossier has been verified as 16-06-2015 (Dy. No R&I: 155).
	Decision:Approved. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
145.	Name and address of manufacturer / Applicant	"M/s Scilife Pharma (Pvt) Ltd, Plot No. FD-57/58-A-2, Korangi Creek, Industrial Park (KCIP) Karachi." Contract manufacturing by M/s Nabiqasim Industries Ltd, 17/24, Korangi Industrial Area, Korangi Highway, korangi, Karachi.
	Brand Name +Dosage Form + Strength	Lomisec IV 40mg injection
	Composition	"Each vial contains: Omeprazole sodium eq. to Omeprazole…….40mg"
	Diary No. Date of R& I & fee	Dy. No R&I : 14325 dated 08-09-2017 (Original dossier) Dy. No R&I : 38068 dated 19-11-2018 Rs.50,000/- Dated 16-06-2015 (Photocopy)
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Innovator specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	RISEK 40MG injection by M/s Julphar Pakistan (Pvt) Ltd (Reg#045617)
	GMP status	**Scilife:** GMP inspection dated 10-07-2018 concluding GMP compliance level is rated as GOOD. **NabiQasim:** GMP inspection dated 02-08-2018 concluding that firm is operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of the Evaluator[II]	The firm has submitted duplicate dossier and as per record retrieved from R & I section forwarded by Reg-I section dated 01-03-2019 (attached with dossier) initial submission date of dossier has been verified as 08-09-2017 (Dy. No R&I: 14325).
	Decision: Approved with innovator's specifications. Registration Board further decided to verify fee challan as per decision of 285th meeting of Registration Board.	
146.	Name and address of manufacturer / Applicant	"M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan"
	Brand Name +Dosage Form + Strength	Wenvax XR 75mg Capsule
	Composition	"Each Extended Release Capsule Contains: Venlafaxine as Hydrochloride…75mg"
	Diary No. Date of R& I & fee	Dy. No 12090 dated 02-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	Serotonin and nor epinephrine reuptake inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Venflax XR 75mg Capsule by M/s Regal Pharmaceuticals (Reg#081978)
	GMP status	GMP inspection dated 30-09-2018 & 29-10-2018 wherein panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator[II]	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall 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.	
147.	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	Linzy 100mg/5ml Dry Suspension
	Composition	"Each 5ml of reconstituted suspension contains: Linezolid……100mg"
	Diary No. Date of R& I & fee	Dy. No 12091 dated 02-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	60ml; As per DRAP's pricing policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	J-Linz dry powder for Suspension by M/s Jupiter Pharma (Reg#081949)
	GMP status	GMP inspection dated 11 & 24-10-2018 wherein panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
148.	Name and address of manufacturer / Applicant	"M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Saltra DPI Powder for Inhalation 50mcg+500mcg

Composition	"Each capsule contains: Salmeterol Xinafoate eq. to Salmeterol……50mcg Fluticasone Propionate……500mcg"
Diary No. Date of R& I & fee	Dy. No 12246 dated 03-04-2018 Rs.20,000/- 03-04-2018
Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excluding Anticholinergics.
Type of Form	Form-5
Finished product Specifications	USP
Pack size & Demanded Price	60's; Rs. 1500/-
Approval status of product in Reference Regulatory Authorities	Advair diskus approved by USFDA
Me-too status (with strength and dosage form)	Seretide Diskus 50/500mcg Powder For Inhalation of M/s Glaxosmithkline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi. (Reg.#074728).
GMP status	GMP inspection dated 26-06-2018 wherein firm was considered to be operating at an acceptable level of compliance with GMP guidelines as of today.

Remarks of the Evaluator[II]

- The applied formulation is approved in USFDA is supplied as a disposable purple plastic inhaler containing a foil blister strip with 60 blisters. The inhaler is packaged in a plastic-coated, moisture-protective foil.

Sr. #	Observations	Response by Firm
i.	Under standardized in vitro test conditions, ADVAIR DISKUS delivers 233mcg of fluticasone propionate and 45mcg of salmeterol base per blister from ADVAIR DISKUS when tested at a flow rate of 60L/min. for 2 seconds while you have not submitted any label claim for delivered dose	Please refer to submitted finished product specification wherein we have mentioned that Delivered-Dose Uniformity should be as per USP monograph i.e., Saltra DPI delivers 233mcg of fluticasone propionate and 45mcg of salmeterol base per capsule when tested at a flow rate of 60L/min. for 2 seconds.
ii.	In reference products referred by you, formulation is pre-dispensed in a foil blister strips, whereas applied formulation is primarily pre-dispensed in hard capsules. Justification shall be submitted for change in primary container closure system with respect to compatibility of applied formulation with the hard gelatin capsule.	This is to bring to your kind attention that DRAP has already approved Salmeterol + Fluticasone propionate DPI 50mcg + 250mcg in hard capsules in its 275th DRB Meeting for M/s Macter International Ltd., Karachi with the brand name of Salmicort DPI (Salmeterol + Fluticasone propionate) Capsules 50mcg + 250mcg (extract attached). In order to confirm the compatibility of applied formulation with hard capsules, this is to inform you that HMPC based capsule shell is inert in nature and has no impact on formulation. Also, the primary packaging of our applied product and reference product is same i.e., Blister foil.
iii.	Clarification regarding intended manufacturing area, since applied formulation contains Fluticasone, which is a steroid.	This is to inform your good office that we have established a segregated facility for the manufacturing of Dry Powder Inhalers (DPI) Capsules. Layout of the said facility has been approved by DRAP (copy of approval letter attached). Further, we have requested Central Licensing Division of DRAP for the constitution of panel for the inspection of our newly established Dry Powder Inhalers (DPI) manufacturing facility (copy of request letter attached). We hereby declared that after registration of 'Saltra DPI', the said product will be manufactured in our segregated DPI manufacturing facility.

	Decision: Deferred for further deliberation upon manufacturing requirement of applied formulation.	
149.	Name and address of manufacturer / Applicant	"M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Saltra DPI Powder for Inhalation 50mcg+250mcg
	Composition	"Each capsule contains: Salmeterol Xinafoate eq. to Salmeterol……50mcg Fluticasone Propionate……250mcg"
	Diary No. Date of R& I & fee	Dy. No 12245 dated 03-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excluding Anticholinergics.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	60's; Rs. 1200/-
	Approval status of product in Reference Regulatory Authorities	Advair diskus approved by USFDA
	Me-too status (with strength and dosage form)	Seretide Diskus 50/250mcg Powder For Inhalation of M/s Glaxosmithkline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi. (Reg. #074727).
	GMP status	GMP inspection dated 26-06-2018 wherein firm was considered to be operating at an acceptable level of compliance with GMP guidelines as of today.

Remarks of the Evaluator[II]

- The applied formulation is approved in USFDA is supplied as a disposable purple plastic inhaler containing a foil blister strip with 60 blisters. The inhaler is packaged in a plastic-coated, moisture-protective foil.

Sr. #	Observations	Response by Firm
i.	Under standardized in vitro test conditions, ADVAIR DISKUS delivers 465mcg of fluticasone propionate and 45mcg of salmeterol base per blister from ADVAIR DISKUS when tested at a flow rate of 60L/min. for 2 seconds while you have not submitted any label claim for delivered dose	Please refer to submitted finished product specification wherein we have mentioned that Delivered-Dose Uniformity should be as per USP monograph i.e., Saltra DPI delivers 233mcg of fluticasone propionate and 45mcg of salmeterol base per capsule when tested at a flow rate of 60L/min. for 2 seconds.
ii.	In reference products referred by you, formulation is pre-dispensed in a foil blistered strips, whereas applied formulation is primarily pre-dispensed in hard capsules. Justification shall be submitted for change in primary container closure system with respect to compatibility of applied formulation with the hard gelatin capsules.	This is to bring to your kind attention that DRAP has already approved Salmeterol + Fluticasone propionate DPI 50mcg + 500mcg **in hard capsules** in its 275th DRB Meeting for M/s Macter International Ltd., Karachi with the brand name of Salmicort DPI (Salmeterol + Fluticasone propionate) Capsules 50mcg + 500mcg (extract attached). In order to confirm the compatibility of applied formulation with hard capsules, this is to inform you that HMPC based capsule shell is inert in nature and has no impact on formulation. Also, the primary packaging of our applied product and reference product is same i.e., Blister foil.
iii.	Clarification regarding intended manufacturing area, since applied formulation contains Fluticasone, which is a steroid.	This is to inform your good office that we have established a segregated facility for the manufacturing of Dry Powder Inhalers (DPI) Capsules. Layout of the said facility has been approved by DRAP (copy of approval letter attached). Further, we have requested Central Licensing Division of DRAP for the constitution of

			panel for the inspection of our newly established Dry Powder Inhalers (DPI) manufacturing facility (copy of request letter attached). We hereby declared that after registration of 'Saltra DPI', the said product will be manufactured in our segregated DPI manufacturing facility.
	Decision: Deferred for further deliberation upon manufacturing requirement of applied formulation.		
150.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK"	
	Brand Name +Dosage Form + Strength	Ceclofin SR-200 Tablets	
	Composition	"Each Sustained Release film coated Tablet Contains: Aceclofenac……200mg"	
	Diary No. Date of R& I & fee	Dy. No 12244 dated 03-04-2018 Rs.20,000/- 03-04-2018	
	Pharmacological Group	NSAID	
	Type of Form	Form-5	
	Finished product Specifications	Manufacturer's specifications	
	Pack size & Demanded Price	As recommended by the PRC	
	Approval status of product in Reference Regulatory Authorities	--	
	Me-too status (with strength and dosage form)	Alkeris SR 200mg Tablet of Sami Pharmaceuticals, Karachi (Reg. #061066).	
	GMP status	GMP inspection dated 12/05/18 concluding that overall the firm was operating under Good level of cGMP.	
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.		
151.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"	
	Brand Name +Dosage Form + Strength	Pekny 550mg Tablets	
	Composition	"Each Film Coated Tablet Contains: Rifaximin…550mg"	
	Diary No. Date of R& I & fee	Dy. No 12254 dated 03-04-2018 Rs.20,000/- 03-04-2018	
	Pharmacological Group	Antibiotics	
	Type of Form	Form-5	
	Finished product Specifications	Manufacturer's specifications	
	Pack size & Demanded Price	2 x 5's, 10's ; As per SRO	
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK	
	Me-too status (with strength and dosage form)	Rixago 550mg Tablet by M/s OBS Pharma Karachi (Reg#081073)	
	GMP status	GMP inspection dated 10-10-2018 & 17-10-2018 wherein the panel unanimously recommends for grant of GMP certificate.	
	Remarks of the Evaluator[II]		
	Decision:Approved with innovator's specification.		
152.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"	
	Brand Name +Dosage Form + Strength	Pekny 200mg Tablets	
	Composition	"Each Film Coated Tablet Contains: Rifaximin…200mg"	
	Diary No. Date of R& I & fee	Dy. No 12253 dated 03-04-2018 Rs.20,000/- 03-04-2018	
	Pharmacological Group	Antibiotics	
	Type of Form	Form-5	
	Finished product Specifications	Manufacturer's specifications	

	Pack size & Demanded Price	2 x 5's, 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Normix Tablets by M/s Sanital Pharmaceutical Rawalpindi. (Reg#022656)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
153.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"
	Brand Name +Dosage Form + Strength	Mozart 1mg/ml Oral Solution
	Composition	"Each ml Contains: Risperidone……1mg"
	Diary No. Date of R& I & fee	Dy. No 12251 dated 03-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Risperdal Oral Solution by M/s Johnson & Johnson Ltd Karachi. (Reg.# 027396)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
154.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Medmox 400mg Tablets
	Composition	"Each Film Coated Tablet Contains: Moxifloxacin as HCl……400mg"
	Diary No. Date of R& I & fee	Dy. No 12454 dated 04-04-2018 Rs. 20,000/- 29-03-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5's; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Navelox Tablets 400mg by M/s Navegal Laboratories (Reg# 068237)
	GMP status	Last inspection dated 12-01-2018 for grant of new DML. Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
155.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries (Pvt) Ltd, 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 3mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….3mg"
	Diary No. Date of R& I & fee	Dy. No 12312 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Becalm 3mg Tablet of M/s Maple Pharmaceuticals, Karachi (Reg.# 058206)
	GMP status	Last inspection dated 13-02-2018 concluding as under: "Overall the firm was in good working condition and following the cGMP guidelines as per Drugs Act, 1976 and rules framed there under, Based on the area inspected the people met and document reviewed and considering the findings of Inspection of M/s Say don Pharmaceuticals Pvt. Ltd Peshawar is considered at acceptable level of compliance with CGMPguidelines as per Drugs Act, 1976 and rules framed under." (No of Recommendations written by Area FID in the detail report after conclusion.) **Recommendations:** The management is advised to appoint fill time QA In charge with sufficient experience and testing of their products, according to Pharmacopeia methods. All the above points discuss with the management and they are agreed to rectify at their earliest. The HPLC operator and microbiologist need training. The firm is further advised to purchase latest official books. The firm is also directed to upgrade their SOPs for "Sterility Testing" and arrange official strains of microbes for media testing."
	Remarks of the Evaluator[II]	
	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.	
156.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…..4mg"
	Diary No. Date of R& I & fee	Dy. No 12313 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Riss 4mg Tablet of M/s M/s Shawan Pharmaceuticals, Islamabad (Reg.# 080376)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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.	
157.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Sebixa 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Memantine HCl……10mg"
	Diary No. Date of R& I & fee	Dy. No 12314 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Stir-UP 10mg Tablets of M/s Nabiqasim Pharmaceuticals (Reg.# 047453)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Sebixa 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Memantine HCl…….10mg"
	Diary No. Date of R& I & fee	Dy. No 12315 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Rement 20mg Table of M/s High-Q Pharmaceuticals, Karachi (Reg.# 073884)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Topadon 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Topiramate…..25mg"
	Diary No. Date of R& I & fee	Dy. No 12316 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Engrax Tablets 100mg of M/s English Pharmaceuticals Industries. (Reg.# 040144)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….2mg"
	Diary No. Date of R& I & fee	Dy. No 12311 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage	Tablet Resjun -2 of M/s Jupiter PharmaPlot # 25, St# S6

	form)	RCCI, Rawat Islamabad. (Reg.# 081922)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Damictal 50mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine…….50mg"
	Diary No. Date of R& I & fee	Dy. No 12320 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sportin 50mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 070345)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Damictal 25mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine……25mg"
	Diary No. Date of R& I & fee	Dy. No 12319 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sportin 25mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 070344)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Resperon 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….1mg"
	Diary No. Date of R& I & fee	Dy. No 12310 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tablet Resjun -1 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081921)

	GMP status	
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Damictal 100mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine……100mg"
	Diary No. Date of R& I & fee	Dy. No 12321 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Epicta 100mg Tablets of M/s Alina Combine Pakistan, Karachi (Reg.# 039081)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Topadon 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Topiramate……50mg"
	Diary No. Date of R& I & fee	Dy. No 12317 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Engrax Tablets 100mg of M/s English Pharmaceuticals Industries. (Reg.# 040144)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Zepidep 15mg Tablet
	Composition	"Each Film Coated Tablet Contains: Mirtazapine Hemihydrate……15mg"
	Diary No. Date of R& I & fee	Dy. No 12326 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mirton-15 Tablets of M/s Genome Pharmaceuticals (Pvt.) Ltd (Reg.# 053546)
	GMP status	As recorded for above application

	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Topadon 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Topiramate……100mg"
	Diary No. Date of R& I & fee	Dy. No 12318 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Topamid 100mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 062311)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Deplam 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Trazodone HCl Eq. to Trazodone…….50mg"
	Diary No. Date of R& I & fee	Dy. No 12325 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Depzodon Tablets of M/s Shaheen Pharmaceuticals, (Reg.# 040907)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	In contrary to reference product approved by USFDA, which is available as uncoated tablet, firm had applied for film coated tablet. Clarification shall be submitted in this regard.
	Decision: Deferred for following: • **Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** • **Submission of revised formulation as per reference product.**	
169.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Perica 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…….100mg"
	Diary No. Date of R& I & fee	Dy. No 12324 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Perica 75mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…….75mg"
	Diary No. Date of R& I & fee	Dy. No 12323 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica Capsule by PF Prism (USFDA Approved)
	Me-too status (with strength and dosage form)	Gabica by Getz Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Perica 25mg Capsule
	Composition	"Each Capsule Contains: Pregabalin……25mg"
	Diary No. Date of R& I & fee	Dy. No 12322 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lyrica Capsule by PF Prism (USFDA Approved)
	Me-too status (with strength and dosage form)	Neugast 25mg Capsule by M/s S.J & G, Karachi (Reg.#076771)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	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 Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Brand Name +Dosage Form + Strength	Flow 0.4mg Capsule
	Composition	"Each Capsule Contains: Tamsulosin HCl 0.2% SR Pellets Eq. to Tamsulosin HCl…….0.4mg"
	Diary No. Date of R& I & fee	Dy. No 12322 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	5-alpha reductase inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	M-Sol 0.4mg Capsule of M/s M/s Regal Pharmaceuticals (Reg.#081977)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.
	Decision: Deferred for following: • **Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.** • **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.**	
173.	Name and address of manufacturer / Applicant	"M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura"
	Brand Name +Dosage Form + Strength	Moxamic-A 100mg/ml Injection
	Composition	"Each ml Contains: Tranexamic acid…….100mg"
	Diary No. Date of R& I & fee	Dy. No 12279 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Haemostatic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5ml glass ampoule; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Tremic-500 Injection by M/s Fynk Pharma. (Reg.# 062678)
	GMP status	GMP inspection dated 21-02-2018 concluding as under: "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[II]	
	Decision:Approved.	
174.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Pentowin 40mg Tablets
	Composition	"Each delayed release Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg"
	Diary No. Date of R& I & fee	Dy. No 12290 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Proton pump inhibitor
	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	Approved by MHRA
	Me-too status (with strength and dosage form)	Cantrofast Tablets of M/s Candid Pharmaceuticals (Reg.#082031)
	GMP status	GMP inspection dated 09-102018 concluding as under: "All the observations noted during the inspections were discussed with their CEO and technical persons for earlier compliance. Based on above observations, documentations reviwed and personnel met their overall GMP compliance level is rated as good.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
175.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Drozenel 10mg Tablet

	Composition	"Each film coated Tablet Contains: Ebastine…….10mg"
	Diary No. Date of R& I & fee	Dy. No 12287 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	10's,20's,30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANMS of France
	Me-too status (with strength and dosage form)	Clubex 10mg Tablets of M/s Welmark Pharmaceuticals. (Reg.# 056446)
	GMP status	GMP inspection dated 09-102018 concluding as under: "All the observations noted during the inspections were discussed with their CEO and technical persons for earlier compliance. Based on above observations, documentations reviwed and personnel met their overall GMP compliance level is rated as good.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
176.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Maltin-F Oral Syrup
	Composition	"Each 5ml Contains: Iron III Hydroxide polymaltose complex Eq. to Elemental Iron……..50mg Folic Acid……..0.35mg"
	Diary No. Date of R& I & fee	Dy. No 12289 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Irofin-F Syrup of M/s AlinaCombine Karachi. (Reg.#074893)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
177.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Drozenel 20mg Tablet
	Composition	"Each film coated Tablet Contains: Ebastine…….20mg"
	Diary No. Date of R& I & fee	Dy. No 12288 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	10's,20's,30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Medicine Evaluation Board of Netherland.
	Me-too status (with strength and dosage form)	Lobastin Tablet 20mgTablets of M/s Lowitt Pharmaceutical (Pvt) Ltd. (Reg.# 080844)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	

178.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Maltin-F Tablet
	Composition	"Each chewable Tablet Contains: Iron III Hydroxide Polymaltose Complex Eq. to Elemental Iron ……. 100mg Folic Acid……0.35mg"
	Diary No. Date of R& I & fee	Dy. No 12285 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Anti-anaemic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Ipomalt -F Tablets of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd. (Reg.# 077301)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
179.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Rowin 250mg Tablet
	Composition	"Each film coated Tablet Contains: Azithromycin…….250mg"
	Diary No. Date of R& I & fee	Dy. No 12286 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Macrolide Anti-biotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	A-Mycin 250mg Tablets of M/s Alen Pharmaceuticals (Pvt.) Ltd (Reg.#078510)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
180.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Maltin Oral Drops
	Composition	"Each ml Contains: Iron III Hydroxide polymaltose complex Eq. to Elemental Iron…50mg"
	Diary No. Date of R& I & fee	Dy. No 12291 dated 04-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status	RBC Oral Drops of M/s Genix Pharma (Reg.#076165)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	

181.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Examic 250mg/5ml Injection
	Composition	"Each 5ml ampoule Contains: Tranexamic acid…….250mg"
	Diary No. Date of R& I & fee	Dy. No 12438 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5ml x 10's;As per SRO
	Approval status of product in Reference Regulatory Authorities	Transcermin Note 5% Injection by M/s Daiichi Sankyo Co., Ltd. (PMDA Japan Approved)
	Me-too status (with strength and dosage form)	Tremic-250 Injection by M/s Fynk Pharma. (Reg.# 062677)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10-04-2018, concluding an acceptable level of compliance with good manufacturing practices for Pharma products
	Remarks of the Evaluator[II]	
	Decision:Approved.	
182.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Dimenate 50mg Injection
	Composition	"Each Ampoule Contains: Dimenhydrinate……50mg"
	Diary No. Date of R& I & fee	Dy. No 12436 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antihistamines
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1ml x 25's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada.
	Me-too status (with strength and dosage form)	Misvinate 50mg Injection by M/s Mission Karachi (Reg.# 080319)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
183.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Examic 250mg Capsule
	Composition	"Each Capsule Contains: Tranexamic acid……250mg"
	Diary No. Date of R& I & fee	Dy. No 12437 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA of Japan
	Me-too status (with strength and dosage form)	Tranex 250mgCapsule by M/s Mission Karachi (Reg.# 080311)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	

184.	Name and address of manufacturer / Applicant	"M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Examic 500mg Capsule
	Composition	"Each Capsule Contains: Tranexamic acid……500mg"
	Diary No. Date of R& I & fee	Dy. No 12439 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Italian Medicine Agency
	Me-too status (with strength and dosage form)	Tranex 500mgCapsule by M/s Mission Karachi (Reg.# 080310)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
185.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Sert 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sertraline HCl Eq. to Sertraline…….100mg"
	Diary No. Date of R& I & fee	Dy. No 12519 dated 05-04-2018 Rs. 20,000/- 05-04-2018
	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3 x 10's; As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Ertalin 100 mg Tablets of M/s Genome Pharmaceuticals (Reg.# 076845)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 22/02/2018, concluding good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
186.	Name and address of manufacturer / Applicant	"M/s Pacific Pharmaceuticals Limited. 30 km, Multan Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Phenadrin-P Forte 50/650 mg Tablets
	Composition	"Each Tablet Contains: Orphenadrine Citrate…….50mg Paracetamol……650mg"
	Diary No. Date of R& I & fee	Dy. No 12516 dated 05-04-2018 Rs. 20,000/- 05-04-2018
	Pharmacological Group	Narcotic analgesic combination
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	1 x 10's, 2 x 10's, 3 x 10's, 2 x 12's, 5 x 10's, 10 x 10's; As per brand leader
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Orthoflex-D 50mg Tablet of M/s Noa Hemis Karachi (Reg.# 075984)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
187.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Citolin 100mg Oral Solution
	Composition	"Each ml Contains: Citicoline Sodium Eq. to Citicoline…100mg"
	Diary No. Date of R& I & fee	Dy. No 12536 dated 05-04-2018 Rs.20,000/- 03-04-2018
	Pharmacological Group	CNS stimulant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	30ml, 60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain.
	Me-too status (with strength and dosage form)	Cercolin Syrup of M/s Schazoo Laboratories (Reg.# 048985)
	GMP status	GMP inspection dated 09-102018 concluding as under: "All the observations noted during the inspections were discussed with their CEO and technical persons for earlier compliance. Based on above observations, documentations reviewed and personnel met their overall GMP compliance level is rated as good.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
188.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name +Dosage Form + Strength	Vortox 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine hydrobromide 25.42 Eq. to Vortioxetine…20mg"
	Diary No. Date of R& I & fee	Dy. No 12538 dated 05-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK.
	Me-too status (with strength and dosage form)	Brintellix 20mg tablet by M/s Lundebeck
	GMP status	GMP inspection dated 04-07-2018 concluding good GMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
189.	Name and address of manufacturer / Applicant	"M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan"
	Brand Name +Dosage Form + Strength	Vortox 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vortioxetine Hydrobromide 12.7 Eq. to Vortioxetine…10mg"
	Diary No. Date of R& I & fee	Dy. No 12537 dated 05-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PAC recommendation
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK.

	Me-too status (with strength and dosage form)	Brintellix 10mg tablet by M/s Lundebeck
	GMP status	GMP inspection dated 04-07-2018 concluding good GMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
190.	Name and address of manufacturer / Applicant	"M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Elvox 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levofloxacin Hemihydarte Eq. to Levofloxacin …… 250mg"
	Diary No. Date of R & I & fee	Dy. No 12548 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 130/-
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Tablets 250mg of M/s Actavis Group United (MHRA Approved)
	Me-too status (with strength and dosage form)	Leflox Kingdom Tablets 250mg of M/s Getz Pharma
	GMP status	Last GMP inspection was conducted on 24-09-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[II]	• Scientific justification for using 5% overage of Levofloxacin hemihydrate in the master formulation.
	Decision:Deferred for scientific justification for using 5% overage of Levofloxacin hemihydrate in the master formulation	
191.	Name and address of manufacturer / Applicant	"M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, SITE Super Highway Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Elvox 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levofloxacin Hemihydarte Eq. to Levofloxacin …… 500mg"
	Diary No. Date of R & I & fee	Dy. No 12549 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1 x 10's; Rs. 416/-
	Approval status of product in Reference Regulatory Authorities	Levofloxacin Tablets 500mg of M/s Actavis Group United Kingdom (MHRA Approved)
	Me-too status (with strength and dosage form)	Leflox Tablets 500mg of M/s Getz Pharma
	GMP status	Last GMP inspection was conducted on 24-09-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator[II]	• Scientific justification for using 5% overage of Levofloxacin hemihydrate in the master formulation.
	Decision:Deferred for scientific justification for using 5% overage of Levofloxacin hemihydrate in the master formulation	
192.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Befine 100mg/5ml Suspension
	Composition	"Each 5ml Contains: Ibuprofen…….100mg"
	Diary No. Date of R & I & fee	Dy. No 12594 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	90ml; (As per Govt. policy)

	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Mefen 100mg Suspension of M/s Metro Pharmaceuticals (Reg.# 082038)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
193.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Nocuf DM Syrup
	Composition	"Each 5ml Contains: Diphenhydramine HCl …… 5mg Dextromethorphan HBr …… 6.25mg"
	Diary No. Date of R & I & fee	Dy. No 12593 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Antihistamine/Antitussive
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Kufmed DM Syrup of M/s Fozan Pharmaceuticals (Pvt) Ltd (Reg.# 074514)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
194.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Sertax 50mg Tablets
	Composition	"Each Film Coated Tablet Contains: Sertraline as Hydrochloride……50mg"
	Diary No. Date of R & I & fee	Dy. No 12592 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Ertalin 50 mg Tablets of M/s Genome pharmaceuticals, (Reg.#076844)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
195.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Passulosin 0.4mg SR Capsule
	Composition	"Each Sustained Release Capsule Contains: Tamsulosin Hydrochloride (as modified release pellets).....0.4mg **Source of pellets:** "M/s Spansules Formulations, Hyderabad, India.

	Diary No. Date of R & I & fee	Dy. No 12591 dated 05-04-2018 Rs.20,000/- 05-04-2018 Rs. 80,000/- dated 22-04-2019
	Pharmacological Group	Alpha 1 adrenergic receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Uripro 0.4mg Capsule M/s Getz Pharma (Reg.#081040)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with change of brand name.	
196.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Tri-Fit Plus Tablets
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate……10mg Hydrochlorothiazide…12.5mg Valsartan…….160mg"
	Diary No. Date of R & I & fee	Dy. No 12590 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad. (Reg.# 077749)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with change of brand name.	
197.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Tri-Fit Tablets
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate……5mg Hydrochlorothiazide…….12.5mg Valsartan……160mg"
	Diary No. Date of R & I & fee	Dy. No 12589 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Aldric-H 5/160/12.5mg of M/s Martin Dow Ltd. Karachi. (Reg.# 081152)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with change of brand name.	

198.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Tri-Ase 20mg Tablets
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as Calcium…20mg"
	Diary No. Date of R & I & fee	Dy. No 12588 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Rosunext Tablets 20mg by M/s Novamed Pharma. (Reg.# 064848)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
199.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Tri-Ase 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as Calcium…10mg"
	Diary No. Date of R & I & fee	Dy. No 12587 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Rosunext Tablets 10mg by M/s Novamed Pharma. (Reg.# 064847)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
200.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Tri-Ase 5mg Tablets
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin Calcium…5mg"
	Diary No. Date of R & I & fee	Dy. No 12586 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Cholestrol lowering medicine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Rosat Tablets 5 mg by M/s Genera Pharma. (Reg.# 069984)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved.	

201.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Preleptic 75mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…75mg"
	Diary No. Date of R & I & fee	Dy. No 12583 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Gabica by M/s Getz Pharma
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification and change of brand name.	
202.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Preleptic 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R & I & fee	Dy. No 12582 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Anti epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Gabica by M/s Getz Pharma
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification and change of brand name.	
203.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Alzamantine 10mg Tablets
	Composition	"Each Film Coated Tablet Contains: Memantine HCl…10mg"
	Diary No. Date of R & I & fee	Dy. No 12581 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Psychoanaleptics.
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Dmantin 10mg Tablets by M/s Genome Pharmaceuticals (Reg.#056078)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	

204.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Neutral Plus Suspension
	Composition	"Each 5ml Contains: Aluminium Hydroxide…300mg Magnesium Hydroxide…150mg Simethicon…125mg"
	Diary No. Date of R & I & fee	Dy. No 12585 dated 05-04-2018 Rs.20,000/- 05-04-201
	Pharmacological Group	Antacid & antiflatulent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Simecrol Plus Suspension by M/s Hicon Pharmaceuticals (Reg.#041459)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
205.	Name and address of manufacturer / Applicant	"M/s Dr. Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Neutral Suspension
	Composition	"Each 5ml Contains: Aluminium Hydroxide…215mg Magnesium Hydroxide…80mg Simethicone…….25mg"
	Diary No. Date of R & I & fee	Dy. No 12584 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Antacid & antiflatulent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	(As per Govt. policy)
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	Simecrol Suspension by M/s Hicon Pharmaceuticals (Reg.#041458)
	GMP status	Last inspection dated 24-01-2019 concluding satisfactory cGMP compliance.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
206.	Name and address of manufacturer / Applicant	"M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700"
	Brand Name +Dosage Form + Strength	Graber 120mg Capsule
	Composition	"Each Capsule Contains: Orlistat (as 50% w/w pellets) ……. 120mg" Source of pellets: M/s Alphamed formulations, Pvt. Ltd, Sy. No. 225, Sampanbole Village, Medchal-Malkajgiri District, Telangana, India.
	Diary No. Date of R & I & fee	Dy. No 12281 dated 04-04-2018 Rs.100,000/- 04-04-2018 (Photocopy)

	Pharmacological Group	Anti-obesity
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	30's; As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Orlovit capsules by M/s CCL Pharma (Reg.#046324)
	GMP status	Last inspection report dated 02/05/18 concluding as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process
	Remarks of the Evaluator[II]	Stability data submitted by supplier for Orlistat pellets is not as per Zone-IV A conditions.
	Decision: Deferred for further deliberation upon stability data requirement for orlistat pellets.	
207.	Name and address of manufacturer / Applicant	"M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura"
	Brand Name +Dosage Form + Strength	Moxamic-A 50mg/ml Injection
	Composition	"Each ml Contains: Tranexamic acid…50mg"
	Diary No. Date of R & I & fee	Dy. No 12278 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Fibrinolytic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Transcermin Note 5% Injection by M/s Daiichi Sankyo Co., Ltd. (PMDA Japan Approved)
	Me-too status (with strength and dosage form)	Traxacid 250mg/5ml Injection by M/s Asian Continental (Reg#057865)
	GMP status	GMP inspection dated 21-02-2018 concluding as under: "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[II]	
	Decision:Approved.	
208.	Name and address of manufacturer / Applicant	"M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura"
	Brand Name +Dosage Form + Strength	Metoprolol Tartrate 5mg/5ml Injection
	Composition	"Each 5ml ampoule Contains: Metoprolol Tartrate ……. 5mg"
	Diary No. Date of R & I & fee	Dy. No 12277 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	B-receptor blocker
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	5ml x 5's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Metobar Injection by M/s Barret Hodgson (Reg#076480)
	GMP status	GMP inspection dated 21-02-2018 concluding as under: "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[II]	
	Decision:Approved.	

209.	Name and address of manufacturer / Applicant	"M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke,Sheikhupura"
	Brand Name +Dosage Form + Strength	Baligno Cartridge Injection
	Composition	"Each Catridge (1.8ml) Contains: Lignocaine HCl …… 36mg Epinephrine Bitartrate…0.0324mg"
	Diary No. Date of R & I & fee	Dy. No 12277 dated 04-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Antiarrhythmatic & local anaesthetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Ra. 1352 per 1.8ml x 50's ampoules
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	KWANG MYUNG LIDOCAINE HCL of M/s ALI Pharma Karachi (Reg.# 023645)
	GMP status	GMP inspection dated 21-02-2018 concluding as under: "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[II]	
	Decision: Deferred for evidence of approval of required manufacturing facility for cartridge filling.	
210.	Name and address of manufacturer / Applicant	"M/s Dyson Research Laboratories Pvt Ltd. 28 km Ferozepur Road Lahore"
	Brand Name +Dosage Form + Strength	Timzi 2mg Tablets
	Composition	"Each Tablet Contains: Tizanidine as hydrochloride……2mg"
	Diary No. Date of R & I & fee	Dy. No 12535 dated 05-04-2018 Rs.20,000/- 04-04-2018
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SN Skelax 2 mg Tablets by M/s SNB Pharma (Pvt) Ltd. (Reg#078412)
	GMP status	Last inspection report 01-08-2017 with conclusion that Panel Recommended issuance of GMP certificate to the firm.
	Remarks of the Evaluator[II]	
	Decision: Approved	
211.	Name and address of manufacturer / Applicant	"M/s The Schazoo Zaka Pvt Ltd. Lahore, Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura"
	Brand Name +Dosage Form + Strength	Desvenla XR 100mg Tablet
	Composition	"Each Extended Release tablet Contains: Desvenlafaxine as Succinate ……. 100mg"
	Diary No. Date of R & I & fee	Dy. No 12691 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Rs. 98 per tablet; 1 x 10's
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Desvel XR 100mg Tablet by M/s Hilton Pharma (Reg#070760)
	GMP status	Last inspection report 01-08-2017 with conclusion that Panel Recommended issuance of GMP certificate to the firm.

	Remarks of the Evaluator[II]	
	Decision:Approved.	
212.	Name and address of manufacturer / Applicant	"M/s The Schazoo Zaka (Pvt) Ltd. Lahore, Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura"
	Brand Name +Dosage Form + Strength	Desvenla XR 50mg Tablet
	Composition	"Each Extended Release tablet Contains: Desvenlafaxine as Succinate ……. 50mg"
	Diary No. Date of R & I & fee	Dy. No 12690 dated 05-04-2018 Rs.20,000/- 05-04-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Rs. 60 per tablet; 1 x 10's
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Desvel XR 50mg Tablet by M/s Hilton Pharma (Reg#070761)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
213.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Brand Name +Dosage Form + Strength	Safestin 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pitavastatin Calcium Eq. to Pitavastatin…4mg"
	Diary No. Date of R & I & fee	Dy. No 12308 dated 04-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's,30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Pitalip Tablets 4mg by M/s Hilton Pharma (Reg#070657)
	GMP status	Last inspection report 02-08-2018 concluding satisfactory level of GMP compliance
	Remarks of the Evaluator[II]	• JP monograph is available for applied formulation.
	Decision: Approved with JP specifications and change of brand name.	
214.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Brand Name +Dosage Form + Strength	Safestin 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pitavastatin Calcium Eq. to Piotavastatin……1mg"
	Diary No. Date of R & I & fee	Dy. No 12307 dated 04-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's,30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Pitalip Tablets 1mg by M/s Hilton Pharma (Reg#070655)
	GMP status	Last inspection report 02-08-2018 concluding satisfactory level of GMP compliance
	Remarks of the Evaluator[II]	• JP monograph is available for applied formulation.
	Decision: Approved with JP specifications and change of brand name.	

215.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Brand Name +Dosage Form + Strength	Safestin 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pitavastatin Calcium Eq. to Piotavastatin……2mg"
	Diary No. Date of R & I & fee	Dy. No 12309 dated 04-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's, 20's,30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Pitalip Tablets 2mg by M/s Hilton Pharma (Reg#070656)
	GMP status	Last inspection report 02-08-2018 concluding satisfactory level of GMP compliance
	Remarks of the Evaluator[II]	• JP monograph is available for applied formulation.
	Decision: Approved with JP specifications and change of brand name.	
216.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Brand Name +Dosage Form + Strength	Nimodin 30mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimodipine……30mg"
	Diary No. Date of R & I & fee	Dy. No 12306 dated 04-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	Selective calcium channel blockers
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	10's, 20's,30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status	Uni-Pine 30mg tablet by M/s Uni-tech (Reg#048665)
	GMP status	Last inspection report 02-08-2018 concluding satisfactory level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision:Approved.	
217.	Name and address of manufacturer / Applicant	"M/s Seraph Pharmaceuticals. Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Sympta 20mg Capsule
	Composition	Each Hard Gelatin Capsule Contains: Duloxetine Hydrochloride enteric coated pellets e.q to Duloxetine…20mg"
	Diary No. Date of R & I & fee	Dy. No 6484 dated 21-02-2018 Rs. 20,000/- 21-02-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's, As per PRC.
	Approval status of product in Reference Regulatory Authorities	Cymbalta USFDA Approved.
	Me-too status (with strength and dosage form)	073501; Swenta 20mg Capsule M/s Martin Dow, Karachi.
	GMP status	GMP certificate issue don the basis of inspection conducted on 11-0Source of pellets6-2018.
	Remarks of the Evaluator[V]	
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	

218.	Name and address of manufacturer / Applicant	M/s Bio Mark Pharmaceuticals, Plot No. 527-Sunder Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Spasgo tablet 80mg/80mg
	Composition	Each sugar coated tablet contains: Hydrated Phloroglucinol 80mg corresponding to anhydrous Phloroglucinol…….62.233mg Trimethylphloroglucinol…….80mg
	Diary No. Date of R & I & fee	Dy. No.14498; 11-09-2017; Rs.20,000/- (11-09-2017)
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form-5
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	3x10'; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities	SPASFON (ANSM approved)
	Me-too status (with strength and dosage form)	Spasrid tablets of M/s Barret Hodgson (Reg.# 034743)
	GMP status	GMP certificate issued on the basis of inspection conducted on 16-08-2018.
	Remarks of the Evaluator[V]	
	Decision:Approved with innovator's specification and change of brand name.	
219.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals (Formerly Silver Oak) Plot No.16//1, Phase No.4.4, Industrial Estate Area, Hattar Distt. Haripur."
	Brand Name +Dosage Form + Strength	Qupin SR 300mg tablet
	Composition	"Each sustained release tablet contains: Quetiapne as Fumarate …… 300mg"
	Diary No. Date of R& I & fee	Dy. No R&I : 14325 dated 08-09-2017 (Original dossier) Dy. No R&I : 38068 dated 19-11-2018 Rs.8,000/- Dy. No. 746 dated 13-09-2011/- Rs. 12,000/- Dy. No. 407 dated 28-11-2014 Dated 16-06-2015 (Photocopy)
	Pharmacological Group	Psychotropic agent
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Ziapine-SR Tablets 300mg of M.s English Pharma (Reg.#068002)
	GMP status	GMP inspection dated 12/05/18 concluding that overall the firm was operating under Good level of cGMP.
	Remarks of the Evaluator[II]	Deputy Director (R-IV) vide letter No. F.16-4/2013-Reg-IV dated 26-12-2018 has stated that "Firm could not produce the verified copy for 8,000/- challan, the firm has again submitted fee of Rs. 8,000/- vide challan no. 0811378 dated 21-12-2018. The firm has verified copy of challan of Rs. 12,000/-
	Decision:Approved. Fee verification shall be processed as per decision of registration Board.	
220.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals, Islamabad."
	Brand Name +Dosage Form + Strength	Hydra Lubricant Eye drops
	Composition	"Each ml contains: Sodium hyaluronate …….. 2mg"
	Diary No. Date of R& I & fee	Dy.No.(R&I):123 (08-11-2016), Rs. 20,000/- (08-11-2016)
	Pharmacological Group	Lubricant
	Type of Form	Form-5

	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA
	Me-too status (with strength and dosage form)	Hylo of M/s Helix Pharma (Reg.#067031)
	GMP status	GMP inspection dated 20-03-2018 concluding as under: "Based on the areas inspected the people met and the documents reviewed and considering the findings of the inspection. M/s Noa Hemis Pharma located at Karachi is considered to be operating at an acceptable level of compliance to the cGMP guidelines, however management should put more focus on hiring of adequate qualified persons for further up gradation and strengthens of technical expertise."
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
221.	Name and address of manufacturer / Applicant	"M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi"
	Brand Name +Dosage Form + Strength	Osteo-D 5mg/ml Injection
	Composition	"Each ml Contains: Cholecalciferol…5mg Eq. to 200,000 IU"
	Diary No. Date of R& I & fee	Dy. No 843 dated 05-01-2018 Rs. 20,000 Dated 05-01-2018 (Photocopy)
	Pharmacological Group	Vitamin D
	Type of Form	Form-5 (Duplicate)
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PCA
	Approval status of product in Reference Regulatory Authorities	VITAMIN D3 GOOD 200,000 IU / 1 ml IM solution for injection ANSM, France approved
	Me-too status (with strength and dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 01-10-2018, concluding good level of GMP compliance at the time of inspection.
	Remarks of the Evaluator[II]	
	Decision: Approved with change of brand name. Fee shall be verified as per procedure adopted by Registration Board.	
222.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Valtra Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besyate……10mg Valsartan…320mg Hydrochlorothiazide…25mg"
	Diary No. Date of R& I & fee	Dy. No 6263 dated 20-02-2018 Rs. 20,000/- 20-02-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per Drug pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad. (Reg.# 077753)
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator[2]	

	Decision: Approved.	
223.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Valtra-D Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besyate…5mg Valsartan…160mg Hydrochlorothiazide…25mg"
	Diary No. Date of R& I & fee	Dy. No 6264 dated 20-02-2018 Rs. 20,000/- 20-02-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per Drug pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Aldric-H 5/160/25mg Tablet of M/s Martin Dow Ltd. Karachi (Reg.# 081148)
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator[2]	
	Decision: Approved.	
224.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Valtra-H Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine Besyate…10mg Valsartan…160mg Hydrochlorothiazide…25mg"
	Diary No. Date of R& I & fee	Dy. No 6265 dated 20-02-2018 Rs. 20,000/- 20-02-2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per Drug pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Sofvasc –HCT Tablet of Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad. (Reg.# 077753)
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator[2]	
	Decision: Approved.	

b. Deferred cases

225.	Name and address of manufacturer / Applicant	M/s Pharma Lord (Pvt.) Ltd, 12Km, Lahore Road, Layyah.
	Brand Name +Dosage Form + Strength	Slimax 120mg capsule
	Composition	Each capsule contains: Orlistat IR pellets eq. to Orlistat…….120mg Source of pellets: Vision Pharmaceuticals, Islamabad.
	Diary No. Date of R& I & fee	Dy. No.10017; 25-07-2017; Rs.20,000/- (25-07-2017)
	Pharmacological Group	Anti-obesity
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's; As per SRO 3x10's; As per SRO 10x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xenical 120mg capsule (USFDA Approved)

	Me-too status	Orly capsule 120mg of M/s Rotex Medica Pakistan
	GMP status	26-05-2017-Routine GMP Inspection; Firm is GMP compliant
	Remarks of the Evaluator.	• Firm has submitted only real time stability study data of three batches of pellets for 24 months.
	Previous Decision:	Registration Board in its 282nd meeting deferred for further deliberation upon requirement of accelerated stability study data of Orlistat pellets
	Evaluation by PEC:	• Firm has submitted declaration form M/s Vision Pharmaceuticals (Pvt.) Ltd. as under: "Orlistat melts at about 42°C and its formulation becomes unstable at higher temperature so it's not suitable to perform stability studies at accelerated conditions i.e., 40 ± 2°C and 75% ± 5%, due to this reason accelerated stability studies for orlistat immediate release pellets is not being performed. We are performing only real time stability studies (i.e., 30 ± 2°C and 65% ± 5%).
	Decision: Deferred for further deliberation upon stability data requirement for orlistat pellets.	
226.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Hicar 40/3360 mg Sachet
	Composition	Each sachet Contains: Omeprazole…40mg Sodium Bicarbonate…3360mg
	Diary No. Date of R& I & fee	Dy.No 23472 dated 06-07-2018 Rs.20,000/- 26-06-2018
	Pharmacological Group	Proton Pump Inhibitor/antacid
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Not verifiable
	GMP status	New DML on 13-06-2018
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Previous Decision:	Registration Board in its 284th meeting Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm
	Evaluation by PEC:	• Firm has submitted revised Form5 with following composition: "Each sachet Contains: Omeprazole……40mg Sodium Bicarbonate…1680mg" • Following me-too reference has been verified against revised composition: "Ruling + Sachet of M/s High-Q (Reg.#070633)" • Reference for revised formulation has also been verified from USFDA.

		• Firm has submitted fee of Rs. 20,000/- for revision of formulation vide deposit slip# 0832240 dated 19-03-2019.
	Decision: Approved with followimg composition: **"Each sachet Contains:** **Omeprazole…….....40mg** **Sodium Bicarbonate……..1680mg"**	
227.	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	Lanspro 30mg Capsule
	Composition	"Each Capsule Contains: Lansoprazole (as enteric coated pellets 8.5% w/w)……..30mg"
	Diary No. Date of R& I & fee	Dy. No 1616 dated 11-01-2018 Rs. 20,000 Dated 10-01-2018
	Pharmacological Group	Antipeptic ulcerant
	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	Leazole 30mg Capsules of M/s Leads Pharma (Pvt.) Ltd. (Reg.#035891)
	GMP status	Last GMP inspection report dated 05/10/2017 Panel recommends DML renewal and additional sections
	Remarks of the Evaluator.	
	Previous decision	Registration Board in its 287th meeting 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	Firm has submitted source of "Lansoprazole 8.5% w/w enteric coated pellets" from M/s Vision Pharmaceuticals, Pakistan. Stability data for three batches of pellets has also been submitted as per Zone-Iva conditions, form the M/s Vision Pharmaceuticals, Pakistan.
	Decision:Approved.	
228.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tamflo Capsule
	Composition	Each capsule contains: Tamsulosin hydrochloride (as SR pellets)…..0.4mg
	Diary No. Date of R& I & fee	Dy No. 1174: 15-10-2014 PKR 20,000/-: 02-10-2014
	Pharmacological Group	Selective alpha 1 receptor antagonist
	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.	Diffundox XL 400 microgram Capsules by Winthrop Pharmaceuticals (MHRA Approved)
	Me-too status	Tamsolin capsule by Getz
	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.	Source of pellets along with GMP of manufacturer, stability study data of pellets is not submitted.
	Previous decision	Registration Board in its 287th meeting deferred the case for further deliberation.
	Evaluation by PEC	Firm has submitted source of "Tamsulosin hydrochloride SR pellets 0.2%w/w" from M/s Vision Pharmaceuticals, Pakistan. Stability data for three batches of pellets has also been submitted as per Zone-IVA conditions, form the M/s Vision

		Pharmaceuticals, Pakistan.
	Decision: Approved with change of brand name.	
229.	Name and address of manufacturer / Applicant	M/s Zephyr Pharmatec Pvt. Ltd., A-39, S.I.T.E. II, Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Acurax tablets 400mg
	Composition	Each tablet contains: Doxofylline…….400mg
	Diary No. Date of R& I & fee	Dy. No.6533; 16-06-2017; Rs.20,000/- (14-06-2017)
	Pharmacological Group	Bronchodilator
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10's; As per PRC's price
	Approval status of product in Reference Regulatory Authorities.	Italian Medicine Agency (AIFA) Italy approved
	Me-too status	Profylline tablet 400mg of M/s Kaizen
	GMP status	Last inspection report conducted on 18-07-2017 concluding good level of GMP compliance.
	Remarks of the Evaluator.	• No official monograph of the applied formulation exists in available editions of USP/BP/IP/JP. • Original fee challan for Accurax 500mg tablets is attached instead of Accurax 400mg tablets. • Firm has revised formulation from film coated tablets to uncoated tablets without submission of requisite fee.
	Previous decision	Registration Board in its 283rd meeting deferred for following: • Original fee challan for applied formulation. • Submission of fee for revision of formulation
	Evaluation by PEC	Firm has submitted that erroneously the strength of the product in deposit slip had been mentioned as 500mg whereas the correct strength of the product is 400mg. Now the firm has submitted a new deposit slip of Rs. 20,000/- with correct strength i.e., 400mg as a fee for the registration of subject product vide deposit slip# 0825041 dated 01-04-2019.
	Decision:Approved with innovator's specification	
230.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore **contract manufacturing by:** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Esotac Injection 40mg
	Composition	Each vial contains: Esomeprazole as sodium……40mg
	Diary No. Date of R& I & fee	2132, 05-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Nexum IV 40mg infusion of M/s Getz Pharma (Reg.#050651)
	GMP status	Not provided
	Remarks of the Evaluator.	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last

		1 year. • Form 5 signed by authorized and technical persons. • After being deferred in 285th meeting of Registration Board, the firm has submitted revised master formulation without overage.
	Previous decision	Registration Board in its 286th meeting deferred the case for assessment and confirmation of manufacturing capacity of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	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:Approved with innovator's specification	
231.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore **contract manufacturing by** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Omefin Injection 40mg
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Diary No. Date of R& I & fee	2128, 05-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV of sandoz (TGA)
	Me-too status	Loprot of Nabiqasim
	GMP status	Not provided
	Remarks of the Evaluator.	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • After being deferred in 285th meeting of Registration Board, the firm has submitted revised master formulation without overage.
	Previous decision	Registration Board in its 286th meeting deferred the case for assessment and confirmation of manufacturing capacity of M/s.

		English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	As recorded for above application
	Decision:Approved with innovator's specification	
232.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore **contract manufacturing by** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Fespan Injection 40mg
	Composition	Each vial contains: Pantoprazole as sodium……40mg
	Diary No. Date of R& I & fee	2131, 05-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Protonix by wyeth (USFDA
	Me-too status	Neege by Sami
	GMP status	Not provided
	Remarks of the Evaluator.	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • After being deferred in 285th meeting of Registration Board, the firm has submitted revised master formulation without overage.
	Previous decision	Registration Board in its 286th meeting deferred the case for assessment and confirmation of manufacturing capacity of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	As recorded for above application
	Decision:Approved with innovator's specification	
233.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore **contract manufacturing by** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Naplin Injection 1g
	Composition	Each vial contains: Vancomycin as Hydrochloride ……1 g
	Diary No. Date of R& I & fee	2133, 04-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Glycopeptide antibacterial
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vancomycin 1g of Fresenius Kabi, USA (USFDA
	Me-too status	Vinjec injection by Bosch
	GMP status	Not provided
	Remarks of the Evaluator.	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • After being deferred in 285th meeting of Registration Board, the firm has submitted revised master formulation without overage.
	Previous decision	Registration Board in its 286th meeting deferred the case for assessment and confirmation of manufacturing capacity of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	As recorded for above application
	Decision:Approved with innovator's specification	
234.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore **contract manufacturing by** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Naplin Injection 500mg
	Composition	Each vial contains: Vancomycin as Hydrochloride ……500 mg
	Diary No. Date of R& I & fee	2129, 04-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Glycopeptide antibacterial
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vancomycin 500mg of Fresenius Kabi, USA (USFDA
	Me-too status	Vinjec injection by Bosch
	GMP status	Not provided
	Remarks of the Evaluator.	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • After being deferred in 285th meeting of Registration Board, the firm has submitted revised master formulation without overage.

	Previous decision	Registration Board in its 286th meeting deferred the case for assessment and confirmation of manufacturing capacity of M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	As recorded for above application
	Decision:Approved with innovator's specification	
235.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12-A, Sector 5, I-5, New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Spastop tablets 40mg
	Composition	Each film coated tablet contains: Drotaverine as hydrochloride……40mg
	Diary No. Date of R& I & fee	Dy. No.1304; 23-09-2016; Rs.20,000/- (23-09-2016)
	Pharmacological Group	Non-anticholinergic antispasmodic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2x10's; Rs.40.00/-
	Approval status of product in Reference Regulatory Authorities.	Approved by 3 EMA member states i.e. Poland, Hungary, Latvia
	Me-too status	No-Spa 40mg tablet of M/s Sanofi Aventis
	GMP status	Last GMP inspection conducted on 06-03-2018 and the report concludes that the firm is considered to be operating at satisfactory level of compliance with GMP guidelines.
	Remarks of the Evaluator.	Firm has submitted revised formulation for uncoated tablets
	Previous decision	Registration Board in its 284th meeting deferred for submission of requisite fee for change of formulation.
	Evaluation by PEC	Firm has submitted the fee of Rs. 5,000/- vide deposit slip# 0746032 dated 20-02-2019, for change of formulation of Spastop 40mg tablets.
	Decision: Approved with Innovator's specifications and change of brand name as "uncoated tablet".	
236.	Name and address of manufacturer / Applicant	M/s Cibex (Pvt.) Ltd., F-405, S.I.T.E., Karachi
	Brand Name +Dosage Form + Strength	Cimora 10mg sachet
	Composition	Each sachet contains: Esomeprazole (as magnesium) ECP 8.5%.....10mg Source of granules: Vision Pharmaceuticals
	Diary No. Date of R& I & fee	Dy. No.1375; 29-09-2016; Rs.20,000/- (28-09-2016)
	Pharmacological Group	Anti-rheumatic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	28's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Nexium (USFDA approved)
	Me-too status	Axesom of M/s Highnoon
	GMP status	Certificate of cGMP based on evaluation conducted on 20-09-17 is provided.
	Remarks of the Evaluator.	Firm has submitted original fee challan of Rs. 20,000/- (deposit slip# 0708918) submitted to DRAP on 31-07-2018 for Cimora (Esomeprazole) 10mg sachet.
	Previous decision	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Firm has submitted copy of GMP certificate issued by Add. Director, DRAP Karachi issued on the basis of inspection

		conducted on 25-9-2018
	Decision:Approved with innovator's specification	
237.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd, Plot No. K-219-A, Phase-II, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Cefozil dry suspension 250mg/5ml
	Composition	Each 5ml contains: Cefprozil (as monohydrate)…250mg
	Diary No. Date of R& I & fee	Diary No:15205, 24/04/2018, Rs. 20,000/- (23/04/2018)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as 250mg anhydrous cefprozil
	Me-too status	Vegapro 250mg/5ml dry powder for Suspension of M/s Vega Pharmaceuticals as 250mg anhydrous cefprozil
	GMP status	14-09-2017 Panel recommends grant of Additional sections
	Remarks of the Evaluator.	You have applied for formulation containing Cefprozill monohydrate 250mg/5ml while the reference product approved in USFDA contains cefprozil equivalent to 250mg anhydrous cefprozil per 5ml of constituted suspension, clarification is required in this regard
	Previous decision	Registration Board in its 282nd meeting deferred for clarification of formulation submitted by the firm.
	Evaluation by PEC	Firm has submitted master formulation declaring the content of Ceprozil monohydrate eq. to 250mg of Cefrprozil anhydrous per 5 ml.
	Decision: Approved.	
238.	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	Evoprin 300mg Dispersible Tablet
	Composition	Each dispersible Tablet Contains: Aspirin…300mg
	Diary No. Date of R& I & fee	Dy. No 23556 dated 08-12-2017 Rs. 20,000/- 08-12-2017
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	100's,200's,300's & 600's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	--
	GMP status	Last inspection report dated 25-10-2018 with following recommendations: "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.	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Previous decision	Registration Board in its 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	Following me-too reference against the applied formulation has been verified:

		"Disprin Cold 'n' fever Dispersible tablets of M/s Reckit Benckiser Pak Ltd. (Reg.# 027536)
	Decision: Approved with BP specifications and change of brand name.	
239.	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	Bupion SR 75mg tablets
	Composition	Each sustained release film coated tablet contains: Bupropion hydrochloride……..75mg
	Diary No. Date of R& I & fee	Dy.No.1266;(06-10-2016);Rs.20,000/-(03-10-2016)
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's; As decided by the Ministry of Health
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed in this strength as sustained release tablets
	Me-too status	Wellben SR 75mg tablet of M/s Bosch Pharmaceuticals, Karachi
	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.	➢ **Shortcomings:** • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Previous decision	Registration Board in its 283rd meeting 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.
	Evaluation by PEC	• Firm has requested to change the composition of Bupion SR 75mg tablets to plain film coated tablets due to unavailability of sustained formulation in reference regulatory authorities. • Firm has submitted revised Form 5 and master formulation with following composition: "Each film coated tablet contains: Bupropion hydrochloride……..75mg • Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 0811865 dated 04-02-2019.
	Decision: Approved with following composition: **"Each film coated tablet contains:** **Bupropion hydrochloride……..75mg"**	
240.	Name and address of manufacturer / Applicant	M/s. Farmigea Pakistan (Pvt) Ltd, Lahore
	Brand Name +Dosage Form + Strength	Moxicin 0.5% Eye Drops
	Composition	Each ml contains:- Moxifloxacin HCl……..0.5%w/v
	Diary No. Date of R& I & fee	Dairy No.8991 dated 15.07.2013 Rs:20,000/-
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 195; 5ml
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Eyemox Eye Drops 0.5%. by M/s Vega Pharmaceuticals,

		Lahore (Reg.# 045929)
	GMP status	Last inspection report conducted on 01-02-2018 wherein panel has recommended the resumption of production of steroidal products in the general area as decision of the CLB in its 239th meeting.
	Remarks of the Evaluator.	
	Previous decision	Registration Board in its 258th meeting deferred for following: • Commitment as per 251st meeting of RB is required. • Shelf life is 3years mentioned by the firm Minutes for 258th Registration Board Meeting whereas 2years are allowed by the Board. • Availability is SRA is not provided. • Latest inspection report is required. • Reference Literature for full description of the specification and analytical method for API, Excipients and Finished product is required. • Type of plastic container and compatibility stability of the product with container may also be approved. • Most of documents are not signed by QC Manger and Production In charge.
	Evaluation by PEC	• Firm has submitted that their bottle is with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure. Tamper evidence is provided by a security seal around the closure of the bottle. This container closure system is same as that of the reference product. • Moreover firm has submitted Form 5, rectifying the other shortcomings. • Evidence of international availability has been verified from the MHRA of UK.
	Decision:Deferred for confirmation of manufacturing/packaging facility of bottle with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure.	
241.	Name and address of manufacturer / Applicant	M/s. Farmigea Pakistan (Pvt) Ltd, Lahore
	Brand Name +Dosage Form + Strength	Ocufusic 1% Eye Drops
	Composition	Each ml contains:- Fusidic acid 1%
	Diary No. Date of R& I & fee	Dairy No.9874 dated 21-08-2013 Rs:20,000/-
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	Rs. 180; 5ml
	Approval status of product in Reference Regulatory Authorities.	Fucithalmic 1%w/w viscous eye drops approved by MHRA of UK
	Me-too status	Eyemox Eye Drops 0.5%. by M/s Vega Pharmaceuticals, Lahore (Reg.# 045929)
	GMP status	Last inspection report conducted on 01-02-2018 wherein panel has recommended the resumption of production of steroidal products in the general area as decision of the CLB in its 239th meeting.
	Remarks of the Evaluator.	
	Previous decision	Registration Board in its 258th meeting deferred for following: • Commitment as per 251st meeting of RB is required. • Shelf life is 3years mentioned by the firm Minutes for

		258th Registration Board Meeting whereas 2years are allowed by the Board. • Availability is SRA is not provided. • Latest inspection report is required. • Reference Literature for full description of the specification and analytical method for API, Excipients and Finished product is required. • Type of plastic container and compatibility stability of the product with container may also be approved. • Most of documents are not signed by QC Manger and Production In charge.
	Evaluation by PEC	• Firm has submitted that their bottle is with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure. Tamper evidence is provided by a security seal around the closure of the bottle. This container closure system is same as that of the reference product. • Moreover firm has submitted Form 5, rectifying the other shortcomings. • Evidence of international availability has been verified from the MHRA of UK.
	Decision:Deferred for confirmation of manufacturing/packaging facility of bottle with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure.	
242.	Name and address of manufacturer / Applicant	M/s. Farmigea Pakistan (Pvt) Ltd, Lahore
	Brand Name +Dosage Form + Strength	Ocufusic 1% Eye Drops
	Composition	Each ml contains:- Fusidic acid..... 1%
	Diary No. Date of R& I & fee	Dairy No.9874 dated 21-08-2013 Rs:20,000/-
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	Rs. 180; 5ml
	Approval status of product in Reference Regulatory Authorities.	Fucithalmic 1%w/w viscous eye drops approved by MHRA of UK
	Me-too status	Fusitek Eye Drops by Innvotek pharma (Reg.# 026957)
	GMP status	Last inspection report conducted on 01-02-2018 wherein panel has recommended the resumption of production of steroidal products in the general area as decision of the CLB in its 239th meeting.
	Remarks of the Evaluator.	
	Previous decision	Registration Board in its 264th meeting deferred for following: • Confirmation of container closure system whether as per innovator or otherwise • Clarification of composition as reference product states composition as mg/gm whereas composition of applied product is stated in mg/ml
	Evaluation by PEC	• Firm has submitted that their bottle is with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure. Tamper evidence is provided by a security seal around the closure of the bottle. This container closure system is same as that of the reference product.

		• Reference product is available as tube. • Moreover firm has submitted Form 5, with composition as per reference product as under: "Each gm contains:- Fusidic acid..... 10mg"
	Decision:Deferred for confirmation of manufacturing/packaging facility of bottle with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure.	
243.	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:- 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
	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.	Firm has submitted that they will be using same container closure system as that of the reference product.
	Previous decision	Registration Board in its 288th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Firm has submitted that copy of Last inspection report conducted on 01-02-2018 wherein panel has recommended the resumption of production of steroidal products in the general area as decision of the CLB in its 239th meeting.
	Decision:Deferred for confirmation of manufacturing/packaging facility of bottle with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure.	
244.	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:- 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.	Firm has submitted that they will be using same container closure system as that of the reference product.
	Previous decision	• Registration Board in its 288th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.

	Evaluation by PEC	Firm has submitted that copy of Last inspection report conducted on 01-02-2018 wherein panel has recommended the resumption of production of steroidal products in the general area as decision of the CLB in its 239th meeting.
	Decision:Deferred for confirmation of manufacturing/packaging facility of bottle with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure.	
245.	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:- 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.	Firm has submitted that they will be using same container closure system as that of the reference product.
	Previous decision	Registration Board in its 288th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Firm has submitted that copy of Last inspection report conducted on 01-02-2018 wherein panel has recommended the resumption of production of steroidal products in the general area as decision of the CLB in its 239th meeting.
	Decision:Deferred for confirmation of manufacturing/packaging facility of bottle with Drop-tainer dispensing system consisting of a transparent low density polyethylene bottle and dispensing plug and white polypropylene closure.	
246.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Prolox powder for oral suspension 500mg/5ml
	Composition	When reconstituted, each 5ml contains: Ciprofloxacin (as hydrochloride).....500mg Source of Ciprofloxacin taste masked granules: M/s Surge Laboratories Pakistan
	Diary No. Date of R& I & fee	Dy. No.11896; 15-08-2017; Rs.20,000/- (11-08-2017)
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	15ml; Rs.1200/- 30ml; Rs.2400/- 60ml; Rs.4800/- 90ml; Rs.7200/- 120ml; Rs.9600/-
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Quash 500mg/5ml suspension of M/s Wilshire Lab. Pvt. Ltd.
	GMP status	Panel inspection conducted on 21-07-2017 concludes that firm is operating at the good GMP compliance.
	Remarks of the Evaluator.	• Firm has submitted revised master formulation with following composition: "When reconstituted, each 5ml contains: Ciprofloxacin..... 500mg "

		• Firm has also submitted fee of Rs. 5,000/- for revision of formulation vide deposit slip#. 0821164.
	Previous decision	Registration Board in its 287th meeting for further deliberation upon the salt form of API, in view of reference product.
	Evaluation by PEC	Firm has referred to USP 41 monograph of "Ciprofloxacin suspension", wherein *Ciprofloxacin RS* has been used instead of *Ciprofloxacin HCl RS* for identification and other tests. Hence it could be inferred that Ciprofloxaicn suspension contains Ciprofloaxaicn in base form.
	Decision: Approved with USP specifications as per following composition: **"When reconstituted, each 5ml contains:** **Ciprofloxacin..... 500mg"**	
247.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Prolox powder for oral suspension 250mg/5ml
	Composition	When reconstituted, each 5ml contains: Ciprofloxacin (as hydrochloride).....250mg Source of Ciprofloxacin taste masked granules: M/s Surge Laboratories Pakistan
	Diary No. Date of R& I & fee	Dy. No.11897; 15-08-2017; Rs.20,000/- (11-08-2017)
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	15ml; Rs.600/- 30ml; Rs.1200/- 60ml; Rs.2400/- 90ml; Rs.3600/- 120ml; Rs.4800/-
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Quash 250mg/5ml suspension of M/s Wilshire Lab. Pvt. Ltd.
	GMP status	Panel inspection conducted on 21-07-2017 concludes that firm is operating at the good GMP compliance.
	Remarks of the Evaluator.	• Firm has submitted revised master formulation with following composition: "When reconstituted, each 5ml contains: Ciprofloxacin..... 250mg " • Firm has also submitted fee of Rs. 5,000/- for revision of formulation vide deposit slip#. 0821165.
	Previous decision	Registration Board in its 287th meeting for further deliberation upon the salt form of API, in view of reference product.
	Evaluation by PEC	Firm has referred to USP 41 monograph of "Ciprofloxacin suspension", wherein *Ciprofloxacin RS* has been used instead of *Ciprofloxacin HCl RS* for identification and other tests. Hence it could be inferred that Ciprofloxaicn suspension contains Ciprofloaxaicn in base form.
	Decision: Approved with USP specifications as per following composition: **"When reconstituted, each 5ml contains:** **Ciprofloxacin..... 250mg"** **Diluent shall be as per innovator's product.**	
248.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Prolox powder for oral suspension 125mg/5ml
	Composition	When reconstituted, each 5ml contains: Ciprofloxacin (as hydrochloride).....125mg Source of Ciprofloxacin HCL taste masked granules: M/s Surge Laboratories Pakistan
	Diary No. Date of R& I & fee	Dy. No.11898; 15-08-2017; Rs.20,000/- (11-08-2017)
	Pharmacological Group	Fluoroquinolone antibiotic

	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	15ml; Rs.300/- 30ml; Rs.600/- 60ml; Rs.1200/- 90ml; Rs.1800/- 120ml; Rs.2400/-
	Approval status of product in Reference Regulatory Authorities.	Approved by Registration Board on the recommended dosage basis
	Me-too status	Quash 125mg/5ml suspension of M/s Wilshire Laboratories Pvt. Ltd.
	GMP status	Panel inspection conducted on 21-07-2017 concludes that firm is operating at the good GMP compliance.
	Remarks of the Evaluator.	• Firm has submitted revised master formulation with following composition: "When reconstituted, each 5ml contains: Ciprofloxacin..... 125mg " • Firm has also submitted fee of Rs. 5,000/- for revision of formulation vide deposit slip#. 0821166.
	Previous decision	Registration Board in its 287th meeting for further deliberation upon the salt form of API, in view of reference product.
	Evaluation by PEC	Firm has referred to USP 41 monograph of "Ciprofloxacin suspension", wherein *Ciprofloxacin RS* has been used instead of *Ciprofloxacin HCl RS* for identification and other tests. Hence it could be inferred that Ciprofloxaicn suspension contains Ciprofloaxaicn in base form.
	Decision: Approved with USP specifications as per following composition: **"When reconstituted, each 5ml contains:** **Ciprofloxacin..... 125mg"** **Diluent shall be as per innovator's product.**	
249.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Evilar 400mg Soft Gel Capsule
	Composition	Each Soft Gel Capsule Contains: Alpha tocopheryl acetate……400mg
	Diary No. Date of R& I & fee	Dy.No 19253 dated 28-05-2018 Rs.20,000/- 25-05-2018
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacture specs.
	Pack size & Demanded Price	100's; Rs. 528/-As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not verifiable
	Me-too status	Zescap 400mg capsule Of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd. (Reg.#030626)
	GMP status	New section granted on 25-06-2018
	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.
	Previous decision	Registration Board in its 283rd meeting for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as submitted reference is not verifiable.
	Evaluation by PEC	Following reference submitted by firm has been verified from Austrian Agency for Health and Food Safety: Evit 600 I.E kapseln. The qualitative comnposition of said product declares following equivalency: 1 capsule contains:

		400 mg = 600 I.U. RRR-alpha-tocopherol https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afrLoop=570329877391478&_afrWindowMode=0&_adf.ctrl-state=19hs10qzp3_4
	Decision:Approved with innovator's specification.	

Case No. 02 Registration applications of newly granted DML or New section (Human)

a. New DML (Remaining molecule)

CLB in its 267th meeting held on 31st December, 2018 has considered and approved the grant the Drug Manufacturing License (DML) bby way of formulation to M/ s Dynatis Pakistan (Pvt.) Ltd, Plot No. 710, Sunder Industrial Estate, Lahore with following six sections and accordingly various applications were considered against each sectionin previous meetings of Registration Board as detailed under :

Sr.#	Name of Section	No. of molecules considered in previous Board meetings	Available balance
1.	Tablet Section (General)	10	0
2	Capsule Section (General)	9	1
3.	Sachet Section (General)	3	7
4.	Cream/Ointment Section (General)	8	2
5.	Cream/Ointment Section (Steroidal)	10	0
6.	Lotion Section (General)	6	4

Now the following products have been applied by firm against the remaining balance of priority molecules, which are presented hereby for consideration of Registration Board.

	Capsule Section (General) 2 products/ 1 molecules	
250.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Diltem SR 180mg capsule
	Composition	Each Capsule Contains: Diltiazem hydrochloride (as extended release pellets)....180mg Source of pellets: M/s Alphamed Formulations, India
	Diary No. Date of R& I & fee	Dy. No 12391 dated 06-03-2019 Rs.100,000/- 06-03-2019
	Pharmacological Group	Benzothiazepine derivative
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30's: as per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Perlita SR Capsule of M/s Wilshire Laboratories (Pvt) Ltd; (Reg.# 069206)
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with USP specifications.	
251.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Diltem SR 90mg capsule
	Composition	Each Capsule Contains: Diltiazem hydrochloride (as extended release pellets)….. 90mg Source of pellets: M/s Alphamed Formulations, India
	Diary No. Date of R& I & fee	Dy. No 12390 dated 06-03-2019 Rs.100,000/- 06-03-2019
	Pharmacological Group	Benzothiazepine derivative
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30's: as per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK

	Me-too status	Perlita SR Capsule of M/s Wilshire Laboratories (Pvt) Ltd; (Reg.# 069205)
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with USP specifications.	
Lotion Section (General) 1 products/ 1 molecules		
252.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dynasten 1% Lotion
	Composition	Each gm Contains: Clotrimazole …… 1%
	Diary No. Date of R& I & fee	Dy. No 5838 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	as per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Dandizole Lotion of M/s Wilson's Pharmaceuticals; (Reg.# 037754)
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with USP specifications.	
Cream/Ointment Section (General) 1 products/ 1 molecules		
253.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dexiclo 4% Gel
	Composition	Each gm Contains: Chlorhexidine digluconate 7.1% w/w equivalent to 4% w/w Chlorhexidine
	Diary No. Date of R& I & fee	Dy. No 12388 dated 08-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiseptic & Anti-infective
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	as per DPC
	Approval status of product in Reference Regulatory Authorities.	Recommended in WHO Essential medicine llist
	Me-too status	
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Remarks of the Evaluator	Stability data required.
	Decision: Deferred for confirmation of approval of required manufacturing facility of "Gel section" from CLB. Moreover Board advised for product's stability data for the applied formulation.	

b. New/Additional Section(s).

Case of M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore The CLB in its 269th meeting held on 26-02-2019 has granted New "Dry Powder Vial Injection (Cephalosporin)" to the firm. The firm has applied for 01 molecule (6 products) in the said section.		
254.	Name and address of manufacturer / Applicant	"M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tridon IV 1gm Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1gm"
	Diary No. Date of R& I & fee	Dy. No 5732 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Rezone 1gm Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031980)
	GMP status	Grant of Additional section of "Dry Powder Vial Injection (Cephalosporin)" dated 05-03-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
255.	Name and address of manufacturer / Applicant	"M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tridon IV 500mg Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg"
	Diary No. Date of R& I & fee	Dy. No 5730 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031982)
	GMP status	Grant of Additional section of "Dry Powder Vial Injection (Cephalosporin)" dated 05-03-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
256.	Name and address of manufacturer / Applicant	"M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tridon IM 1gm Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1gm"
	Diary No. Date of R& I & fee	Dy. No 5733 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Amcef Injection of M/s Linear Pharma Rawat (Reg.# 075343)
	GMP status	Grant of Additional section of "Dry Powder Vial Injection (Cephalosporin)" dated 05-03-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	

257.	Name and address of manufacturer / Applicant	"M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tridon IV 250mg Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg"
	Diary No. Date of R& I & fee	Dy. No 5733 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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 Injection IV FDA Approved.
	Me-too status	Wincef 250 mg IV Injection of M/s Wel Wink Pharmaceuticals (Reg.# 078096)
	GMP status	Grant of Additional section of "Dry Powder Vial Injection (Cephalosporin)" dated 05-03-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
258.	Name and address of manufacturer / Applicant	"M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tridon IM 250mg Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone……250mg"
	Diary No. Date of R& I & fee	Dy. No 5729 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	El-cef Injection of M/s Linear Pharma Rawat (Reg.# 075341)
	GMP status	Grant of Additional section of "Dry Powder Vial Injection (Cephalosporin)" dated 05-03-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
259.	Name and address of manufacturer / Applicant	"M/s Don Valley Pharmaceuticals. 31-km, Main Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tridon IM 500mg Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg"
	Diary No. Date of R& I & fee	Dy. No 5731 dated 08-02-2019 Rs.20,000/- Dated 08-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Fotamin IM 500 mg Injection by M/s Vision Pharmaceuticals. (Reg.#030694)
	GMP status	Grant of Additional section of "Dry Powder Vial Injection (Cephalosporin)" dated 05-03-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	

Case of M/s. Aries Pharmaceuticals, (Pvt.) Ltd., I-W, Industrial Estate, Hayatabad, Peshawar. The CLB in its 269th meeting held on 26-02-2019 has granted New "Dry Powder Vial Injection (Cephalosporin)" to the firm. The firm has applied for 08 molecule (26 products) in the said section.		
260.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Aricef Plus IV/IM Injection 1g
	Composition	Each vial contains: Cefoperazone as Sodium…….500mg Sulbactam as Sodium…..……..500mg
	Diary No. Date of R& I & fee	Dy. No 4633 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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 PMDA-Japan
	Me-too status	2Sum Injection 1g of M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
261.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Aricef Plus IV/IM Injection 2g.
	Composition	Each vial contains: Cefoperazone as Sodium…….1000mg Sulbactam as Sodium…..……..1000mg
	Diary No. Date of R& I & fee	Dy. No 4634 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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 2g of M/s Bosch Pharmaceuticals, Karachi (Reg.# 037631)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
262.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Kecef IV/IM Injection 250mg
	Composition	Each vial contains: Cefotaxime as Sodium…….250mg
	Diary No. Date of R& I & fee	Diary No:4642, 01/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Cefotax by Bosch
	GMP status	26-02-2019 Grant of Additional Section.

		Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
263.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Kecef IV/IM Injection 500mg
	Composition	Each vial contains: Cefotaxime as Sodium…….500mg
	Diary No. Date of R& I & fee	Diary No: , 01/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Getex Dry powder Injection 500mg by M/s Amarant from Medicaid, Karachi (Reg#080278)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
264.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Kecef IV/IM Injection 1000mg
	Composition	Each vial contains: Cefotaxime as Sodium…….1000mg
	Diary No. Date of R& I & fee	Diary No: 4644 , 01/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Getex Dry powder Injection 1gm by M/s Amarant from Medicaid, Karachi (Reg#080279)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
265.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Kecef IV/IM Injection 2.0gm
	Composition	Each vial contains: Cefotaxime as Sodium…….2.0gm.
	Diary No. Date of R& I & fee	Diary No: 4645, 01/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Claforan Injection 1gm by M/s Sanofi Aventis from Medicaid, Karachi (Reg#076156)
	GMP status	26-02-2019 Grant of Additional Section.

		Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
266.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arizid IV/IM Injection 250mg.
	Composition	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime…….250mg.
	Diary No. Date of R& I & fee	Dy. No 4635 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Ceplo Injection 250mg IM/IV of M/s Cirin Parma (Pvt.) Ltd, (Reg.# 024415)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	• In contrary to approved by the reference agencies/authorities wherein the applied formulation is approved as Ceftazidime "as pentahydrate" equal to 250mg, you have applied for Ceftazidime "as Sodium" equal to 250mg. Clarification is required in this regard. • Upon communication of above observation, now firm has submitted revised composition as per reference product, which has been corrected above. Moreover firm has submitted Rs. 5,000 for revision of formulation vide deposit slip# 0829912
	Decision:Approved.	
267.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arizid IV/IM Injection 500mg.
	Composition	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime…….500mg.
	Diary No. Date of R& I & fee	Dy. No 4636 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Vegazid 500mg Injection of Vega Pharmaceuticals (Reg.# 078704)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	• In contrary to approved by the reference agencies/authorities wherein the applied formulation is approved as Ceftazidime "as pentahydrate" equal to 500mg, you have applied for Ceftazidime "as Sodium" equal to 500mg. Clarification is required in this regard. • Upon communication of above observation, now firm has submitted revised composition as per reference product, which has been corrected above. Moreover firm has submitted Rs. 5,000 for revision of formulation vide deposit slip# 0829911
	Decision:Approved.	
268.	Name and address of manufacturer /	M/s. Aries Pharmaceuticals, Peshawar

	Applicant	
	Brand Name +Dosage Form + Strength	Arizid IV/IM Injection 1.0gm.
	Composition	Each vial contains: Ceftazidime pentahydrate eq. to Ceftazidime…….1000mg.
	Diary No. Date of R& I & fee	Dy. No 4637 dated 01-02-2019 Rs.20,000/- Dated 01-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Vegazid 1gm Injection of Vega Pharmaceuticals (Reg.# 078705)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	• In contrary to approved by the reference agencies/authorities wherein the applied formulation is approved as Ceftazidime "as pentahydrate" equal to 1000mg, you have applied for Ceftazidime "as Sodium" equal to 1000mg. Clarification is required in this regard. • Upon communication of above observation, now firm has submitted revised composition as per reference product, which has been corrected above. Moreover firm has submitted Rs. 5,000 for revision of formulation vide deposit slip# 0829913
	Decision:Approved.	
269.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Bactocef IM Injection 250mg.
	Composition	Each vial contains: Ceftriaxone as Sodium…….250mg.
	Diary No. Date of R& I & fee	Dy.No 5847 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	El-cef Injection of M/s Linear Pharma Rawat (Reg.# 075341)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
270.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Bactocef IM Injection 500mg.
	Composition	Each vial contains: Ceftriaxone as Sodium…….500mg.
	Diary No. Date of R& I & fee	Dy.No 5848 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Fotamin IM 500 mg Injection by M/s Vision Pharmaceuticals. (Reg.#030694)
	GMP status	26-02-2019 Grant of Additional Section.

		Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
271.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Bactocef IM Injection 1.0gm
	Composition	Each vial contains: Ceftriaxone as Sodium…….1.0gm
	Diary No. Date of R& I & fee	Dy. No 5849 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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	Amcef Injection of M/s Linear Pharma Rawat (Reg.# 075343)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
272.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arizon IV Injection 250mg.
	Composition	Each vial contains: Ceftriaxone as Sodium…….250mg.
	Diary No. Date of R& I & fee	Dy. No 5850 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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 Injection IV FDA Approved.
	Me-too status	Wincef 250 mg IV Injection of M/s Wel Wink Pharmaceuticals (Reg.# 078096)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
273.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arizon IV Injection 500mg.
	Composition	Each vial contains: Ceftriaxone as Sodium…….500mg.
	Diary No. Date of R& I & fee	Diary No: 5851, 11/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031982)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	

	Decision:Approved.	
274.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arizon IV Injection 1.0gm.
	Composition	Each vial contains: Ceftriaxone as Sodium…….1.0gm.
	Diary No. Date of R& I & fee	Diary No:5852, 11/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Rezone 1gm Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031980)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
275.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arizon IV Injection 2.0gm.
	Composition	Each vial contains: Ceftriaxone as Sodium…….2.0gm.
	Diary No. Date of R& I & fee	Dy. No 5853 dated 11-02-2019 Rs.20,000/- Dated 11-02-2019
	Pharmacological Group	Cephalosporin Antibiotic
	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 Injection IV FDA Approved.
	Me-too status	ANTRIX Injection I.V of M/s Fynk Pharmaceuticals, (Reg.# 077172)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
276.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arirox IV/IM Injection 250mg.
	Composition	Each vial contains: Cefuroxime as Sodium…….250mg.
	Diary No. Date of R& I & fee	Diary No: 2424 , 11/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Cefulite powder Injection by M/s Elite Pharma (Reg.#067747)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
277.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar

	Brand Name +Dosage Form + Strength	Arirox IV/IM Injection 750mg.
	Composition	Each vial contains: Cefuroxime as Sodium…….750mg.
	Diary No. Date of R& I & fee	Diary No: 2423, 11/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Astalexim 750mg Injection by M/s Astellas Pharmaceuticals, Peshawar (Reg.#079751)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
278.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arirox IV/IM Injection 1.5gm.
	Composition	Each vial contains: Cefuroxime as Sodium…….1.5gm.
	Diary No. Date of R& I & fee	Diary No: 2415 , 11/02/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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	Astalexim 1.5g Injection by M/s Astellas Pharmaceuticals, Peshawar (Reg.#079750)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
279.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefgen IV Injection 500mg.
	Composition	Each vial contains: Cefpirome Sulfate Eq. to Cefpirome …….500mg.
	Diary No. Date of R& I & fee	Diary No: 9615, 01/03/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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.	Cefrom Injection Approved by ANSM of France
	Me-too status	Welrome Dry Powder Injection by M/s Welwrd Pharmaceutical (Reg.# 040372)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
280.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefgen IV Injection 1000mg.
	Composition	Each vial contains:

		Cefpirome Sulfate Eq. to Cefpirome …….1000mg.
	Diary No. Date of R& I & fee	Diary No: 9616, 01/03/2019 , Rs: 20,000/-
	Pharmacological Group	Cephalosporin Antibiotic
	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.	Cefrom Injection Approved by ANSM of France
	Me-too status	Welrome Dry Powder Injection by M/s Welwrd Pharmaceutical (Reg.# 040373)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	
281.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefradin IV/IM Injection 250mg.
	Composition	Each vial contains: Cephradine L-Arginine Eq. to Cephradine …….250mg.
	Diary No. Date of R& I & fee	Dy. No 9612 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Velosef Injection by GSK-Pakistan
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
282.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Cefradin IV/IM Injection 500mg.
	Composition	Each vial contains: Cephradine L-Arginine Eq. to Cephradine …….500mg.
	Diary No. Date of R& I & fee	Dy. No 9613 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefril-A Injection Bristol-Myers Squibb
	Me-too status	Velosef Injection by GSK-Pakistan
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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	
283.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar

	Brand Name +Dosage Form + Strength	Cefradin IV/IM Injection 1000mg.
	Composition	Each vial contains: Cephradine L-Arginine Eq. to Cephradine …….1000mg.
	Diary No. Date of R& I & fee	Dy. No 9614 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefril-A Injection Bristol-Myers Squibb
	Me-too status	Velosef Injection by GSK-Pakistan
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted 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.	
284.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arimep IV/IM Injection 500mg.
	Composition	Each vial contains: Cefepime HCl L-Arginine Eq. to Cefepime…….500mg.
	Diary No. Date of R& I & fee	Dy. No 9617 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME Injection Hospira (USAFDA Approved)
	Me-too status	Gepin Dry Powder Injection 500mg by M/s Amarant from Medicaid Karachi. (Reg.#080281)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision: Approved.	
285.	Name and address of manufacturer / Applicant	M/s. Aries Pharmaceuticals, Peshawar
	Brand Name +Dosage Form + Strength	Arimep IV/IM Injection 1000mg.
	Composition	Each vial contains: Cefepime HCI L-Arginine Eq. to Cefepime…….1000mg.
	Diary No. Date of R& I & fee	Dy. No 9618 dated 01-03-2019 Rs.20,000/- Dated 01-03-2019
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME Injection Hospira (USAFDA Approved)
	Me-too status	Gepin Dry Powder Injection 1gm by M/s Amarant from Medicaid Karachi. (Reg.#080282)
	GMP status	26-02-2019 Grant of Additional Section. Panel recommends grant of Additional Section.
	Remarks of the Evaluator.	
	Decision:Approved.	

Case of M/s TAS. Pharmaceuticals (Pvt.) Ltd, Islamabad.

The CLB in its 267th meeting held on 31.12.2018 has granted New Capsule Section (General) to the firm. The firm

has applied for 04 molecules (6 products) in the New Capsule Section (General).		
286.	Name and address of manufacturer / Applicant	TAS. Pharmaceuticals (Pvt.) Ltd, Plot No 209, Kahuta Tiangle, Humak Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	BIOESO 20mg Capsule
	Composition	Each hard gelatin Capsule contains: Enteric coated pellets of Esomeprazole Magnesium trihydrate equivalent to Esomeprazole ……. 20mg. **Source of pellets:** M/s Vision Pharmaceuticals, Islamabad
	Diary No. Date of R& I & fee	Diary No 11345, Dated 05/03/2019, Rs 20000/- , Dated 04/03/2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Unit price & pack size as per DRAP policy.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Esopol Capsule 20mg of M/s Hassan Pharmaceuticals (Pvt.) Ltd., (Reg.# 064143)
	GMP status	Grant of Additional section of "Capsule Section (General)" dated 17-01-2019.
	Remarks of the Evaluator.	• Firm has submitted Rs. 5,000/- vide deposit slip# 1934510 dated 07-05-2019 for revision of formulation
	Decision:Approved.	
287.	Name and address of manufacturer / Applicant	TAS. Pharmaceuticals (Pvt) Ltd, Plot No 209, Kahuta Tiangle, Humak Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	BIOESO 40mg Capsule
	Composition	Each hard gelatin Capsule contains: Enteric coated pellets of Esomeprazole Magnesium trihydrate equivalent to Esomeprazole ……. 40mg. **Source of pellets: M/s Vision Pharmaceuticals, Islamabad**
	Diary No. Date of R& I & fee	Diary No 11346, Dated 05/03/2019, Rs 20000/- , Dated 04/03/2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Unit price & pack size as per DRAP policy.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Esopol Capsule 40mg of M/s Hassan Pharmaceuticals (Pvt) Ltd., (Reg.# 064144)
	GMP status	Grant of Additional section of "Capsule Section (General)" dated 17-01-2019.
	Remarks of the Evaluator.	• Firm has submitted Rs. 5,000/- vide deposit slip# 1934510 dated 07-05-2019 for revision of formulation
	Decision: Approved.	
288.	Name and address of manufacturer / Applicant	TAS. Pharmaceuticals (Pvt) Ltd, Plot No 209, Kahuta Tiangle, Humak Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	BIOZOLE 20mg Capsule
	Composition	Each hard gelatin Capsule contains: Enteric coated pellets of Omeprazole equivalent to Omeprazole ……. 20mg. **Source of pellets:** M/s Vision Pharmaceuticals, Islamabad
	Diary No. Date of R& I & fee	Diary No 11347, Dated 05/03/2019, Rs 20000/- , Dated 04/03/2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	Unit price & pack size as per DRAP policy.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ruling 20 mg Capsule of M/s High-Q (Reg.#044191)
	GMP status	Grant of Additional section of "Capsule Section (General)" dated 17-01-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
289.	Name and address of manufacturer / Applicant	TAS. Pharmaceuticals (Pvt) Ltd, Plot No 209, Kahuta Tiangle, Humak Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	BIOZOLE 40mg Capsule
	Composition	Each hard gelatin Capsule contains: Enteric coated pellets of Omeprazole equivalent to Omeprazole ……. 40mg. Source of pellets: M/s Vision Pharmaceuticals, Islamabad
	Diary No. Date of R& I & fee	Diary No 11348, Dated 05/03/2019, Rs 20000/- , Dated 04/03/2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Unit price & pack size as per DRAP policy.
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA
	Me-too status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	Grant of Additional section of "Capsule Section (General)" dated 17-01-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
290.	Name and address of manufacturer / Applicant	TAS. Pharmaceuticals (Pvt) Ltd, Plot No 209, Kahuta Tiangle, Humak Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	TASOCIN 250mg Capsule
	Composition	Each hard gelatin Capsule contains: Azithromycin Di-hydrate equivalent to Azithromycin … 250mg
	Diary No. Date of R& I & fee	Diary No 11349, Dated 05/03/2019, Rs 20000/- 04/03/2019
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Unit price & pack size as per DRAP policy.
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Exthro 250mg Capsule by M/s Indus Pharma. (Reg.# 055935)
	GMP status	Grant of Additional section of "Capsule Section (General)" dated 17-01-2019.
	Remarks of the Evaluator.	
	Decision: Approved.	
291.	Name and address of manufacturer / Applicant	TAS. Pharmaceuticals (Pvt) Ltd, Plot No 209, Kahuta Tiangle, Humak Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	TASOLINE 0.4mg Capsule
	Composition	Each hard gelatin Capsule contains : Tamsulosin HCl sustained release pellets equivalent to Tamsulosin HCl…… 0.4mg. Source of pellets: M/s Vision Pharmaceuticals, Islamabad
	Diary No. Date of R& I & fee	Diary No 11350, Dated 05/03/2019, Rs 20000/- , Dated 04/03/2019

	Pharmacological Group	Alpha Adrenergic Blockers
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Unit price & pack size as per DRAP policy.
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Uripro 0.4mg Capsule M/s Getz Pharma (Reg.#081040)
	GMP status	Grant of Additional section of "Capsule Section (General)" dated 17-01-2019.
	Remarks of the Evaluator.	• Firm has submitted Rs. 5,000/- vide deposit slip# 1934512 dated 07-05-2019 for revision of formulation
	Decision: Approved.	

Case of "M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore"

The CLB in its 269th meeting held on 26-02-2019 has granted New "General Lyophilization section" to the firm. Now the firm has applied for 10 molecules/13 products as presented under:

292.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Neuvir 500mg Injection
	Composition	"Each Vial Contains: Acyclovir …500mg"
	Diary No. Date of R& I & fee	Dy. No 5123 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Aclovir 500mg Powder for Infusion by M/s Genix Karachi (Reg.#073691)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Salt form of Acyclovir is not mentioned in Form 5 and master formulation. • Reference product is available in Lyophilized cake form, whereas submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification/ justification shall be submitted in this regard. • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted as under: • Revised Form 5 with following revised composition: "Each Vial Contains: Acyclovir as sodium …500mg" • Revised master formulation & manufacturing outline for the production of applied product by way of Lyophilization resulting in the formation of Lyophilization cake. • Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 1918568 dated 08-05-2019.
	Decision: Approved as per following composition: **"Each Lyophilized Vial Contains:** **Acyclovir ….. 500mg"**	
293.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Noxi 8mg Injection
	Composition	"Each Vial Contains:

		Lornoxicam……..8mg"
	Diary No. Date of R& I & fee	Dy. No 5110 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (Austria Approved)
	Me-too status	Viltaz Injection 8mg/2ml by M/s Wilshire Laboratories Lahore (Reg. # 077112)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Reference product is available in Lyophilized cake form, whereas submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification/ justification shall be submitted in this regard. • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted as under: • Revised Form 5 with revised master formulation & manufacturing outline for the production of applied product by way of Lyophilization resulting in the formation of Lyophilization cake. • Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 1918570 dated 08-05-2019.
	Decision: Approved as per following composition: "Each Lyophilized Vial Contains: Lornoxicam……..8mg"	
294.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Petra 40mg Injection
	Composition	"Each Vial Contains: Esomeprazole as Sodium…40mg"
	Diary No. Date of R& I & fee	Dy. No 5115 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Nexium IV of M/s Astrazeneca Pharms approved by USFDA
	Me-too status	Nexum IV 40mg Injection by M/s Getz Pharma, Karachi (Reg#050651)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved with innovator's specification	
295.	Name and address of manufacturer /	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road,

	Applicant	Lahore"
	Brand Name +Dosage Form + Strength	Lan-30 Injection
	Composition	"Each Vial Contains: Lansoprazole……..30mg"
	Diary No. Date of R& I & fee	Dy. No 5117 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Prevacid IV Injection, Takeda Pharmaceuticals USA, (USFDA approved)
	Me-too status	Belenz Injection 30mg by M/s Wellborne Pharmachem Hattar. (Reg#054894)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved with innovator's specification	
296.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Azineu 500mg Injection
	Composition	"Each Vial Contains: Azithromycin…….500mg"
	Diary No. Date of R& I & fee	Dy. No 5114 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Zithromax Injection by M/s Biocare Pharmaceutica, Lahore (Reg.#053895)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved.	
297.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Omeneu 20mg Injection
	Composition	"Each Vial Contains: Omperazole as sodium…….20mg"
	Diary No. Date of R& I & fee	Dy. No 5119 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019

	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	--
	Me-too status	--
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	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 could not be verified. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm could not be verified.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting could not be verified.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm could not be verified.**	
298.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Caprenen 1g Injection
	Composition	"Each Vial Contains: Capreomycin as Sulphate…….1gm"
	Diary No. Date of R& I & fee	Dy. No 5124 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Capacin injection 1gm of M/s Hoffmann Human Health Pakistan ltd., Lahore (Reg.# 043062)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved.	
299.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	V.Zde 200mg/Vial Injection
	Composition	"Each Vial Contains: Voriconazole…….200mg"
	Diary No. Date of R& I & fee	Dy. No 5121 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Anti fungal
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification

	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Vfend 200mg powder for solution for injection MHRA Approved
	Me-too status	Vivid Injection 200mg by M/s S.J & G Karachi (Reg#070582)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved with innovator's specification	
300.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Neupanto 40mg Injection
	Composition	"Each Vial Contains: Pantoprazole as Sodium……40mg"
	Diary No. Date of R& I & fee	Dy. No 5120 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Pantoprazole 40mg Powder for Solution for Injection or Infusion. By M/s TEVA UK Limited (MHRA Approved)
	Me-too status	Pazole Dry Powder Injection IV 40mg by M/s Fynk Pharmaceuticals (Reg#081267)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved with innovator's specification.	
301.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Neuvir 250mg Injection
	Composition	"Each Vial Contains: Acyclovir ……. 250mg"
	Diary No. Date of R& I & fee	Dy. No 5123 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK

	Me-too status	Aclovir 250mg Powder for Infusion by M/s Genix Karachi (Reg.#073690)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Salt form of Acyclovir is not mentioned in Form 5 and master formulation. • Reference product is available in Lyophilized cake form, whereas submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification/ justification shall be submitted in this regard. • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted as under: • Revised Form 5 with following revised composition: "Each Vial Contains: Acyclovir as sodium …250mg" • Revised master formulation & manufacturing outline for the production of applied product by way of Lyophilization resulting in the formation of Lyophilization cake. • Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 1918569 dated 08-05-2019.
	Decision: Approved as per following composition: "Each Lyophilized Vial Contains: Acyclovir ….. 250mg"	
302.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Claromy 500mg Injection
	Composition	"Each Vial Contains: Clarithromycin as Lactobionate…500mg"
	Diary No. Date of R& I & fee	Dy. No 5113 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Maclacin 500mg Injection by M/s Bosch, Karachi (Reg#061080)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Reference product approved by MHRA is available in Lyophilized cake form, whereas submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification/ justification shall be submitted in this regard. • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted as under: • Revised Form 5 with revised master formulation & manufacturing outline for the production of applied product by way of Lyophilization resulting in the formation of Lyophilization cake. • Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 1918571 dated 08-05-2019.

	Decision:Approved.	
303.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Petra 20mg Injection
	Composition	"Each Vial Contains: Esomeprazole as Sodium……20mg"
	Diary No. Date of R& I & fee	Dy. No 5116 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Nexium IV of M/s Astrazeneca Pharms approved by USFDA
	Me-too status	Pep-Ease 20mg Injection by M/s Safe Karachi (Reg#070827)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved with innovator's specification	
304.	Name and address of manufacturer / Applicant	"M/s Neutro Pharma (Pvt.) Ltd. 9.5 km, Sheikhupura Road, Lahore"
	Brand Name +Dosage Form + Strength	Omeneu 40mg Injection
	Composition	"Each Vial Contains: Omperazole as sodium…….40mg"
	Diary No. Date of R& I & fee	Dy. No 5118 dated 06-02-2019 Rs.20,000/- Dated 06-02-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per pricing policy
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	RISEK 40MG injection by M/s Julphar Pakistan (Pvt) Ltd (Reg#045617)
	GMP status	Grant of Additional section of "General Lyophilization section" dated 29-01-2019.
	Remarks of the Evaluator.	• Submitted master formulation & manufacturing outline declare that ready to fill powder is being filled in the vials. Clarification shall be submitted whether firm has facility of dry powder filling in their approved "General Lyophilization section." • Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 25-04-2019, firm has submitted that we have both facilities of Lyophilized cake form and ready to fill powder in vial.
	Decision:Approved with innovator's specification.	

Case No. 03 Registration applications for Local Manufacturing of (Veterinary) Drugs.

a. New Cases

305.	Name and address of manufacturer / Applicant	"M/s S.J & G Fazul Ellahie Pvt Ltd. E-46, S.I.T.E. Karachi-75700"
	Brand Name +Dosage Form + Strength	Lox 50mg Injection
	Composition	"Each ml Contains: Flunixin Meglumine Eq. to Flunixin…50mg"
	Diary No. Date of R & I & fee	Dy. No 12280 dated 04-04-2018 Rs.20,000/- Dated 04-04-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	50ML, 100ML
	Me-too status (with strength and dosage form)	Fluean injection by M/s Leads Pharma (Pvt.) LTD., Islamabad (Reg.#034589)
	GMP status	Last inspection report dated 02/05/18 concluding as under: "The firm has complied/improved according to the directions of the FID. Panel was satisfied for the improvements under taken by the firm to comply with the observations dated 12th July 2017. Further the panel advised the firm to continue the improvements process
	Remarks of the Evaluator[II]	
	Decision:Approved.	
306.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Monasin 20% Premix
	Composition	"Each Kg Contains: Monensin Sodium…….200gm"
	Diary No. Date of R & I & fee	Dy. No 13012 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	1Kg, 5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	MONENSIN 20% PREMIX by M/s VETMED (REGD) LAHORE (Reg.#025305)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved.	
307.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Toxisorb Powder
	Composition	"Each Kg Contains: Silicon Dioxide……69.1% Aluminium Trioxide…….18.9% Feric Oxide……5.75% Magnesium Oxide…….2.92% Sodium Oxide……..0.53%"
	Diary No. Date of R & I & fee	Dy. No 13008 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Mineral mixture
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg, 2.5Kg,5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	MYCO-AD POWDER by M/s TAROBINA CORP LAHORE (Reg.#020841)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.

	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification	
308.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Tylofen Injection
	Composition	"Each 100ml Contains: Tylosin Tartrate……. 15gm Gentamycin Sulphate…….6gm Dexamethasone as Sodium Phosphate…..… 0.0265gm Chlorophenramine (Maleate)……. 0.750gm"
	Diary No. Date of R & I & fee	Dy. No 13034 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Antibiotic, anti-inflammatory and antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	Clear glass vials of 10ml, 20ml, 30ml, 50ml,100ml.
	Me-too status (with strength and dosage form)	Genta Combisone Injection by M/s Leads Pharma (Pvt) Ltd., Islamabad (Reg.#046696)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision: RegistrationBoard referred the case to "Expert Veterinary Group for Veterinary Drugs" for review of formulation.	
309.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Piperax Water Soluble Powder
	Composition	"Each kg Contains: Piperazine Citrate…500gm"
	Diary No. Date of R & I & fee	Dy. No 13027 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Anthalmentic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg, 5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	Pipera-G Water Soluble Powder by M/s GALLIPHARM International Rawalpindi. (Reg.#020105)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification	
310.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Novazyme Powder
	Composition	"Each 100gm Contains: Cellulase…… 4200,000 IU Xylanase….. 2500,000 IU Phytase…200,000 IU Alpha Amylase…….700,000 IU Pectinase……. 50,000 IU"
	Diary No. Date of R & I & fee	Dy. No 13005 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Enzymes
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg,2.5Kg, 5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	NATUZYME POWDER by M/s GHAZI BROTHERS, KARACHI (Reg.#034512)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.

	Remarks of the Evaluator[II]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm since submitted reference is of different composition. • Upon communication of above observation firm has submitted revised Form 5 with following composition as per me-too reference : "Each 1000gm Contains: Cellulase…… 4200,000 IU Xylanase….. 2500,000 IU Phytase…200,000 IU Alpha Amylase…….700,000 IU Pectinase……. 50,000 IU Calcium carbonate ….. 500gm" • Firm has also submitted fee of Rs. 5,000/- vide dated 08-05-2019 for revision of formulation.
	Decision: Registration Board did not accede with firm's request for revision of formulation with inclusion of an additional API and deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
311.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Hi-Pyrine Injection
	Composition	"Each ml Contains: Antipyrine…….400mg"
	Diary No. Date of R & I & fee	Dy. No 13013 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	Clear glass vials of 10ml, 20ml, 30ml, 50ml,100ml.
	Me-too status (with strength and dosage form)	ANTIPIRINA-40 INJECTION by M/s SELJUK INC ISLAMABAD (Reg.#020093)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision: RegistrationBoard referred the case to "Expert Veterinary Group for Veterinary Drugs" for review of formulation.	
312.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Mylan 250 Premix
	Composition	"Each Kg Contains: Tylosin Tartrate……250gm"
	Diary No. Date of R & I & fee	Dy. No 13028 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg,5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	TYLAN PREMIX 250 by M/s ELI LILLY PAKISTAN, (Reg.#013730)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm since submitted reference is of different composition. • Upon communication of above observation firm has submitted

		revised Form 5 with following composition as per me-too reference : "Each Kg Contains: Tylosin phosphate …… 250gm" • Firm has also submitted fee of Rs. 5,000/- vide dated 08-05-2019 for revision of formulation.
	Decision: Approved with change of brand ame as per following composition: **"Each Kg Contains:** **Tylosin phosphate …… 250gm"**	
313.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Toxifix Plus Powder
	Composition	"Each Kg Contains: Calcium Propionate…8.9% Fumaric Acid & lactic acid……2.4% Butylated Hydroxianisole…….0.2%"
	Diary No. Date of R & I & fee	Dy. No 13011 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Calcium supplement and acidifier
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg,5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	TOXI BIND DRY POWDER by M/s VET PHARMA GUJRANWALA (Reg.#020823)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
314.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Betamax Powder
	Composition	"Each gm Contains: Betaine Anhydrous…97%"
	Diary No. Date of R & I & fee	Dy. No 13010 dated 06-04-2018 Rs.20,000/- Dated 27-02-201
	Pharmacological Group	Dietary supplement
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg,5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	BETAFIN SCR POWDER by M/s U.M.ENTERPRISES KARACHI. (Reg.#018420)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification	
315.	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Enrex 80 Premix
	Composition	"Each kg Contains: Enramycin……80gm"
	Diary No. Date of R & I & fee	Dy. No 13009 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	1Kg,5Kg, 10Kg, 20Kg, 25Kg
	Me-too status (with strength and dosage form)	ENRAMYCIN F.80 by M/s HOECHST PHARMACEUTICAL KARACHI (Reg.#015483)
	GMP status	Last inspection report dated 13 & 14-09-2018 recommending

		renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
316.	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Eva 100ml Injection
	Composition	"Each ml Contains: L-arginine HCL...1.44mg L-cysteine HCL...3.20mg L-glutamine...3.20mg Glycine...3.20mg L-histidine...1.32mg L-isoleucine HCL...3.60mg L-leucine HCL...4.28mg L-lysine HCL...5.44mg L-methionine...3.20mg L-threonine...3.20mg L-tryptophan...0.86mg L-phenylalanine...5mg L-valine...3.60mg Thiamine HCL...4mg Riboflavin Sod. Phosphate...0.171mg Pyridoxine HCL...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg"
	Diary No. Date of R & I & fee	Dy. No 10007 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Vitamins, amino acids & mineral supplement.
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100ml glass container
	Me-too status	Ami-Vicom Injection by M/s Selmore Lahore (Reg.#016294)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
317.	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Amoxiclox 50/100 mg Injection
	Composition	"Each ml Contains: Cloxacillin as Sodium…50mg Amoxicillin as Trihydrate…….100mg"
	Diary No. Date of R & I & fee	Dy. No 10012 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Penicillin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100ml glass vial
	Me-too status (with strength and dosage form)	Clomix injection by M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg.#049680)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	

318.	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Amoxiclox 50/100 mg Injection
	Composition	"Each ml Contains: Cloxacillin as Sodium…50mg Amoxicillin as Trihydrate…….100mg"
	Diary No. Date of R & I & fee	Dy. No 10011 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Penicillin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	50ml glass vial
	Me-too status (with strength and dosage form)	Clomix injection by M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi. (Reg.#049680)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
319.	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Cloxam 100ml Injection
	Composition	"Each ml Contains: Ampicillin as Trihydrate…125mg Cloxacillin as Sodium…125mg"
	Diary No. Date of R & I & fee	Dy. No 10010 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Penicillin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100ml glass vial
	Me-too status (with strength and dosage form)	Ampicox injection by M/s Alina Nawan Laboratories (Reg.#035061)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
320.	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Eva 250ml Injection
	Composition	"Each ml Contains: L-arginine HCL...1.44mg L-cysteine HCL...3.20mg L-glutamine...3.20mg Glycine...3.20mg L-histidine...1.32mg L-isoleucine HCL...3.60mg L-leucine HCL...4.28mg L-lysine HCL...5.44mg L-methionine...3.20mg L-threonine...3.20mg L-tryptophan...0.86mg L-phenylalanine...5mg L-valine...3.60mg Thiamine HCL...4mg Riboflavin Sod. Phosphate...0.171mg Pyridoxine HCL...0.34mg Nicotinamide...8mg Ascorbic Acid...4mg

		Glucose...33mg Calcium Chloride...0.08mg Potassium Chloride...0.21mg Magnesium Sulphate...0.08mg"
	Diary No. Date of R & I & fee	Dy. No 10008 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Vitamins, amino acids & mineral supplement.
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100ml glass container
	Me-too status (with strength and dosage form)	AMI-VICOM INJECTION by M/s SELMORE AGENCIES LAHORE (Reg.#016294)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	Evidence of Me-too status in applied fill volume is required.
	Decision: Deferred for evidence of me-too status in applied fill volume.	
321.	Name and address of manufacturer / Applicant	"M/s Prix Pharmaceutica Pvt Ltd.Plot No 5, Pharmacity, 30-km Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Pri-en 20 Injection
	Composition	"Each ml Injection Contains: Enrofloxacin…200mg"
	Diary No. Date of R & I & fee	Dy. No 10302 dated 20-03-2018 Rs.20,000/- Dated 20-03-2018
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	100ml glass container
	Me-too status (with strength and dosage form)	AN-CIN INJECTION by M/s Elko organization (Reg.#031596)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specification.	
322.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobienrox 24% Liquid
	Composition	Each 100ml contains:- Enrofloxacin……..…10gm Aminophyllin……...4gm Guaifenesin……...10gm
	Diary No. Date of R& I & fee	Dy. No.975; 24-08-2016; Rs.20,000/- (24-8-2016)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml
	Me-too status	Anrox solution by bio labs Reg # 033240
	GMP status	Copy of GMP inspection report dated 16-11-2018 concluding as under: "GMP is a continual improvement process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Noble Pharmaceuticals AJK has basic facilities for manufacturing and testing of pharmaceuticals(Vet). At the time of inspection the firm was operating at an average level of GMP; the areas of improvement have been discussed and agreed by the representatives if the firm."
	Remarks of the Evaluator.	Firm has Veterinary Oral liquid (General) section.
	Decision:Approved with innovator's specification.	

323.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Azad Kashmir
	Brand Name +Dosage Form + Strength	Flodox-C Oral Liquid
	Composition	Each 100ml contains:- Florfenicol ……..11gm Colistin Sulphate…….50MIU
	Diary No. Date of R& I & fee	Dy. No.533; 8-06-2016; Rs.20,000/- (8-6-2016)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100ml, 500ml, 1000ml
	Me-too status	Flo raft oral liquid by nawal pharma Reg # 078252
	GMP status	Copy of GMP inspection report dated 16-11-2018 concluding as under: "GMP is a continual improvement process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Noble Pharmaceuticals AJK has basic facilities for manufacturing and testing of pharmaceuticals(Vet). At the time of inspection the firm was operating at an average level of GMP; the areas of improvement have been discussed and agreed by the representatives if the firm."
	Remarks of the Evaluator.	Firm has Veterinary Oral liquid(General) section.
	Decision: Approved with innovator's specification.	
324.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Azad Kashmir
	Brand Name +Dosage Form + Strength	Uniflor-C oral solution/Liquid
	Composition	Each 1000ml contains:- Florfenicol ……..230gm Colistin Sulphate…….50MIU
	Diary No. Date of R& I & fee	Dy. No.532; 8-06-2016; Rs.20,000/- (8-6-2016)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	100ml, 500ml, 1000ml
	Me-too status	C-flor by Bio-oxine Reg # 074782
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Firm has veterinary oral powder(General), veterinary Oral liquid(General), Veterinary Liquid Vials Injection(General)
	Decision: Approved with innovator's specification.	
325.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobien 20% Injection IM
	Composition	Each ml solution contains:- Enrofloxacin……20%
	Diary No. Date of R& I & fee	Dy. No.535; 8-06-2016; Rs.20,000/- (8-6-2016)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	50ml, 100ml
	Me-too status	Enroquin Forte Injection by Mehran int Karachi Reg # 019045
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Firm has Veterinary Liquid Vials Injection(General)
	Decision:Approved with innovator's specification. Moreover Registration Board directed the firm to select one fillvolume only for applied formulation.	

326.	Name and address of manufacturer / Applicant	M/s Noble Pharma, Azad Kashmir
	Brand Name +Dosage Form + Strength	Nobien 10% Injection
	Composition	Each ml solution contains:- Enrofloxacin……10%
	Diary No. Date of R& I & fee	Dy. No.534; 8-06-2016; Rs.20,000/- (8-6-2016)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	50ml, 100ml
	Me-too status	SYVAQUINOL-100 INJECTION by SEIGNOR PHARMA KARACH Reg # 019084
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Firm has Veterinary Liquid Vials Injection(General)
	Decision:Approved with innovator's specification. Moreover Registration Board directed the firm to select one fill volume only for applied formulation.	

b. Deferred Cases

327.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	WARM-NIL Plus Oral Liquid
	Composition	Each 100ml contains: Levamisole HCl …….. 1.5gm Oxyclozanide …… 3.0gm Cobalt sulphate ……. 0.382gm
	Diary No. Date of R& I & fee	Dy. No 5125 dated 12-08-2015 Rs.20,000/-
	Pharmacological Group	Antibacterial/ Dewormer
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Decontrolled/ 100ml, 500ml, 1L, 2.5 L , 5 L & 25 L
	Me-too status	--
	GMP status	GMP inspection dated 16-10-2018 concluding fair level of GMP compliance.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 253rd meeting deferred for confirmation of me-too status.
	Evaluation by PEC:	• Following me-too reference submitted by firm has been verified against the applied formulation: "Vital Cure Oral Drench of M/s Prix Pharmaceutical (Pvt.) Ltd., Lahore. (Reg.# 063690)
	Decision: Approved with innovator's specifications.	
328.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	TETZOLE Oral Liquid
	Composition	Each 100ml contains: Toltrazuril….2.5gm Vitamin K3…..0.3gm
	Diary No. Date of R& I & fee	Dy. No 5128 dated 12-08-2015 Rs.20,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Decontrolled/ 100ml, 500ml, 1L, 2.5 L , 5 L & 25 L
	Me-too status	Coccitol Liquid of M/s Grand Pharma (Pvt) Ltd., RCCI Rawat (Reg.# 062029)
	GMP status	GMP inspection dated 16-10-2018 concluding fair level of GMP compliance.

	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 253rd meeting deferred for clarification of Pharmacological group submitted.
	Evaluation by PEC:	Firm has submitted that previously pharmacological group was submitted erroneously and requested to consider the pharmacological group as "Anti-protozoal agent against Coccidiosis" as correct pharmacological group for applied formulation.
	Decision: Approved with Innovator's Specification.	
329.	Name and address of manufacturer / Applicant	M/s Noble Pharma Plot No. B-1, Old Industrial Area, Mirpur AJK, Pakistan.
	Brand Name +Dosage Form + Strength	Nobifenda oral suspension
	Composition	Each 100ml contains: Oxfendazole…….2.265%w/v Oxyclozanide…….6.25%w/v Cobalt sulphate…….0.167%w/v Sodium selinate……..0.05%w/v
	Diary No. Date of R& I & fee	Dy No. 14204: 7-09-2017 PKR 20,000/-: 6-9-2017
	Pharmacological Group	Anthelmintic / De wormer
	Type of Form	Form 5
	Finished product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1L Pack : Decontrolled
	Me-too status	Crefenda Oral Suspension by Delux Chemicals Indusrties (Reg.#058746)
	Approval status of product in Reference Regulatory Authorities.	N/A
	GMP status	Last inspection report dated 08-11-2016: Firm is GMP compliant
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 286th meeting referred the case to QA & LT Division for updated GMP status of the firm.
	Evaluation by PEC:	Copy of GMP inspection report dated 16-11-2018 concluding as under: "GMP is a continual improvement process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Noble Pharmaceuticals AJK has basic facilities for manufacturing and testing of pharmaceuticals(Vet). At the time of inspection the firm was operating at an average level of GMP; the areas of improvement have been discussed and agreed by the representatives if the firm."
	Decision: Approved with innovator's specifications.	
330.	Name and address of manufacturer / Applicant	M/s Noble Pharma Plot No. B-1, Old Industrial Area, Mirpur AJK, Pakistan.
	Brand Name +Dosage Form + Strength	Nobimint 10% Powder
	Composition	Each 100g contains: Amantadine HCl……10gm
	Diary No. Date of R& I & fee	Dy No. 14205: 7-09-2017 PKR 20,000/-: 6-9-2017
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	100g, 250g, 500g, 1Kg Jar : Decontrolled
	Me-too status	Amantabak 10% powder by Attabak Pharma
	Approval status of product in Reference Regulatory Authorities.	N/A
	GMP status	Last inspection report dated 08-11-2016: Firm is GMP compliant
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 286th meeting referred the case to QA & LT Division for updated GMP status of the firm.

	Evaluation by PEC:	Copy of GMP inspection report dated 16-11-2018 concluding as under: "GMP is a continual improvement process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Noble Pharmaceuticals AJK has basic facilities for manufacturing and testing of pharmaceuticals(Vet). At the time of inspection the firm was operating at an average level of GMP; the areas of improvement have been discussed and agreed by the representatives if the firm."
	Decision: Approved with innovator's specifications.	
331.	Name and address of manufacturer / Applicant	M/s Noble Pharma Plot No. B-1, Old Industrial Area, Mirpur AJK, Pakistan.
	Brand Name +Dosage Form + Strength	Fighter suspension
	Composition	Each 100ml contains: Albendazole……10g Ivermectin……0.2g Triclabendazole…….12g
	Diary No. Date of R& I & fee	Dy No. 14206: 7-09-2017 PKR 20,000/-: 6-9-2017
	Pharmacological Group	Anthelmintic / De wormer
	Type of Form	Form 5
	Finished product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1L Pack : Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Thunder Drench by Star labs
	GMP status	Last inspection report dated 08-11-2016: Firm is GMP compliant
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 286th meeting referred the case to QA & LT Division for updated GMP status of the firm.
	Evaluation by PEC:	Copy of GMP inspection report dated 16-11-2018 concluding as under: "GMP is a continual improvement process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Noble Pharmaceuticals AJK has basic facilities for manufacturing and testing of pharmaceuticals(Vet). At the time of inspection the firm was operating at an average level of GMP; the areas of improvement have been discussed and agreed by the representatives if the firm."
	Decision: Approved with innovator's specifications and change of brand name.	
332.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals. 5-km, Sargodha-Sidhar Bypass Road, Faisalabad
	Brand Name +Dosage Form + Strength	Apla Flush Oral Powder
	Composition	"Each 100gm Contains: Hexamehtylenetetramine…96.5gm Riboflavin…….1gm Calcium Pantothenate…0.5gm Nicotinamide…2.5gm"
	Diary No. Date of R& I & fee	Dy.No 29868 dated 05-09-2018 Rs.20,000/- Dated 05-09-2018
	Pharmacological Group	Antibacterial/Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	500gm, 1Kg, 2.5 Kg, 5Kg in plastic jars; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Arenal Powder of M/s Leads Pharma, Islamabad (Reg.#035197)
	GMP status	New DML granted on 29-08-2018
	Remarks of the Evaluator.	

	Previous Decision of 285th Meeting:	Deferred for clarification/justification of quantities of active pharmaceutical ingredients (APIs) in grams per 100gm.
	Evaluation by PEC:	• Firm has submitted that composition of their applied product "Apla Flush" was written incorrect. We are therefore humbly requesting to kindly change the composition of the product as follows: "Each 100gm Contains: Hexamehtylenetetramine…95.5gm Riboflavin…….1gm Calcium Pantothenate…0.5gm Nicotinamide…2.5gm" • Firm has submitted Fee of Rs. 5,000/- vide deposit slip#0794615 dated 12-03-2019 for revision of formulation. • Following me-too reference against the revised composition has been verified: Z-Renal Water Soluble Powder of M/s Zoic International, Lahore. (Reg.# 080946)
	Decision: Approved with innovator's specifications as per following composition: **"Each 100gm Contains:** **Hexamehtylenetetramine…...95.5gm** **Riboflavin……..1gm** **Calcium Pantothenate……..0.5gm** **Nicotinamide……..2.5gm"**	
333.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	Coliran 25% Oral Solution
	Composition	Each 100ml contains: 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
	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 the Evaluator.	Fee challan Photocopy attached. Me-too status could not be confirmed.
	Previous Decision:	Registration Board in its 288th 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. Only the pack sizes, already approved by Registration Board for generic / me-too product will be given.
	Evaluation by PEC:	• Firm has submitted that the formulation was written mistakenly and now they have submitted revised Form 5 with following composition: "Each 100ml contains: Colistin Sulphate……480 MIU". • Firm has submitted Rs. 5,000/- for revision of formulation vide deposit slip# 0714713 dated 02-05-2019 • Following me too reference has been verified against the revised formulation. "Colostine Oral Liquid of M/s D-Maarson Pharmaceuticals, (Reg.#078360)"
	Decision: Approved with innovator's specifications as per following composition: **"Each 100ml contains:** **Colistin Sulphate……480 MIU"**	

334.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	DIGESTON-P ORAL POWDER
	Composition	Each 1000gm contains:- Propoinic acid calcium……250g Propoinic acid sodium……..400g Acetanilide……150g Magnesium Oxide……125g Iron Sulphate……400mg Zinc Sulphate……100mg Magnesium Sulphate…….200mg Copper Sulphate……450mg Cobalt Sulphate……400mg Sodium Molybdate……...100mg Sodium Chloride……...20g
	Diary No. Date of R& I & fee	Dy. No. 1375, 13-01-2017, 20,000/-, 13-01-2017
	Pharmacological Group	Minerals
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	10g, 15g, 25g, 50g, 100g, 250g, 500g, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg; Decontrolled
	Me-too status	Alvegest powder of Star Laboratories
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Remarks of the Evaluator.	Me-too status could not be confirmed.
	Previous Decision:	Registration Board in its 287th 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:	• Following me too reference has been verified against the revised formulation. "BIOGEST ORAL POWDER of M/s BIO-OXIME PHARMACEUTICALS, (Reg.#0074791)"
	Decision: Approved with innovator's specifications.	
335.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals (Pvt) Ltd., 25-Km Lahore Road, Multan
	Brand Name +Dosage Form + Strength	SUPER COLI POWDER
	Composition	Diary No. Nil (Duplicate), 20,000/-, (Photocopy attached) 25-05-2016
	Diary No. Date of R& I & fee	Each 100gm contains:- Colistin Sulphate……...25.00gm
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	100g, 500g, 1Kg, 2.5Kg, 5Kg, 25Kg; Decontrolled
	Me-too status	N/A
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Remarks of the Evaluator.	• The submitted me-too reference is of different strength.
	Previous Decision:	Registration Board in its 287th 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 submitted that the formulation was written mistakenly and now they have submitted revised Form 5 with following composition: "Each 100gm contains:-

		Colistin Sulphate……...24.00gm" • Following me too reference has been verified against the revised formulation. "Colimicin Powder of M/s Leads Pharma (Pvt.) ltd., Islamabad (Reg.#044971)"
	Decision: Approved with innovator's specifications and change of brand name as per following composition: **"Each 100gm contains:-** **Colistin Sulphate……...24.00gm"**	
336.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals (Pvt) Ltd., 25-Km Lahore Road, Multan
	Brand Name +Dosage Form + Strength	TCD-35 Oral Powder
	Composition	Each 100gm contains: Tylosin tartrate……10gm Doxycycline HCl….20gm Colistine Sulphate….45 MIU 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
	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 the Evaluator.	Fee challan Photocopy attached. Me-too status could not be confirmed.
	Previous Decision:	Registration Board in its 287th 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 submitted that the formulation was written mistakenly and now they have submitted revised Form 5 with following composition: "Each 100gm contains: Tylosin tartrate……10gm Doxycycline HCl….20gm Colistine Sulphate….45 MIU Bromhexine HCl…. 0.4gm" • Firm ha ssubmitted Rs. 5,000/- for revision of formulation vide deposit slip# 0714712. • Following me too reference has been verified against the revised formulation. "DOXYLINE WATER SOLUBLE POWDER of M/s NSHAL PHARMACEUTICAL INDUSTRIES (Reg.#075776)"
	Decision: Decision: Approved with innovator's specifications as per following composition: **"Each 100gm contains:-** **Tylosin tartrate……10gm** **Doxycycline HCl….20gm** **Colistine Sulphate….45 MIU** **Bromhexine HCl…. 0.4gm"**	
337.	Name and address of manufacturer / Applicant	M/s. Ras Pharmaceuticals (Pvt) Ltd., 25-Km Lahore Road, Multan
	Brand Name +Dosage Form + Strength	AMPRO C-50 Oral Powder
	Composition	Each gram contains: - Amprolium HCl …… 500mg

	Diary No. Date of R& I & fee	Diary No:19403, 30-10-2017 , Rs: 20,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per policy of DRAP.
	Me-too status	BIO-AMP 50% POWDER (Reg.# 023410)
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 288th meeting deferred for submission of correct pharmacological group.
	Evaluation by PEC:	• Firm has submitted correct pharmacological group as "Antiprotozoal agent against Coccidiosis"
	Decision: Approved.	
338.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	SPIROX-10 Oral Powder
	Composition	Diary No:5138, 12-08-2015 , Rs: 20,000/-
	Diary No. Date of R& I & fee	Each 100gm contains: Spiramycin……10gm Doxycycline HCl……10gm Bromhexine HCl….2gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	Decontrolled/ 100gm, 500gm, 1kg, 2.5kg, 5kg, & 25 kg
	Me-too status	--
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 287th meeting deferred for confirmation of me-too status.
	Evaluation by PEC:	Following me-too reference submitted by firm has been verified: AS-PLUS WATER SOLUBLE POWDER of M/s ATTABAK PHARMACEUTICAL ISLAMABAD. (Reg.# 071063)
	Decision: Approved with innovator's specifications.	

Case No. 04 Registration Applications of Categories to be Considered on Priority.

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

339.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Tofanib 5mg Tablets
	Composition	"Each Tablet Contains: Tofacitinib as Citrate …… 5mg"
	Diary No. Date of R& I & fee	Dy. No 36787 dated 06-11-2018 Rs.20,000/- Dated 06-11-2018
	Pharmacological Group	Immunosuppresants
	Type of Form	Form-5
	Finished product Specifications	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 (with strength and	NA

	dosage form)	
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	• 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: • **Evidence o f approval of required manufacturing facility for "Cytotoxic drugs" from CLB.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
340.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Tofanib 10mg Tablets
	Composition	"Each Tablet Contains: Tofacitinib as Citrate …… 10mg"
	Diary No. Date of R& I & fee	Dy. No 36788 dated 06-11-2018 Rs.20,000/- Dated 06-11-2018
	Pharmacological Group	Immunosuppressants
	Type of Form	Form-5
	Finished product Specifications	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 (with strength and dosage form)	NA
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	• 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: • **Evidence o f approval of required manufacturing facility for "Cytotoxic drugs" from CLB.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
341.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Famylex 500mg Tablets
	Composition	"Each Film Coated Tablet Contains: Famciclovir…500mg"
	Diary No. Date of R& I & fee	Dy. No 36309 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018
	Pharmacological Group	Antivirals for systemic use
	Type of Form	Form-5
	Finished product Specifications	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 (with strength and dosage form)	Miclovir Tablets 500mg of M/s Cirin Pharmaceuticals, (Reg.# 070361)
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	
342.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Famylex 250mg Tablets
	Composition	"Each Film Coated Tablet Contains: Famciclovir…250mg"
	Diary No. Date of R& I & fee	Dy. No 36308 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018
	Pharmacological Group	Antivirals for systemic use

	Type of Form	Form-5
	Finished product Specifications	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 (with strength and dosage form)	Miclovir Tablets 250mg of M/s Cirin Pharmaceuticals, (Reg.# 064496)
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	
343.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Fingo 0.5mg Capsule
	Composition	"Each Capsule Contains: Fingolimod HCl 0.55mg Eq. to Fingolimod …0.5mg"
	Diary No. Date of R& I & fee	Dy. No 36302 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018
	Pharmacological Group	Immunosuppressants
	Type of Form	Form-5
	Finished product Specifications	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	--
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	• 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.	
344.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Naxia 500mg Capsule
	Composition	"Each Capsule Contains: Hydroxyurea……500mg"
	Diary No. Date of R& I & fee	Dy. No 36305 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018
	Pharmacological Group	Immunosuppressants
	Type of Form	Form-5
	Finished product Specifications	Other antineoplastic agents
	Pack size & Demanded Price	USP
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Hydrine Capsules 500mg by M/s Al-Habib (Reg#022625)
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[II]	• Evidence of approval of required manufacturing facility of "Capsule (Oncology) section" from Central Licensing Board.
	Decision: Deferred for Evidence of approval of required manufacturing facility of "Capsule (Oncology) section" from Central Licensing Board.	
345.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Medomide 100mg Capsule
	Composition	"Each Capsule Contains: Thalidomide…….100mg"
	Diary No. Date of R& I & fee	Dy. No 37192 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Other Immunosuppresants

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Thalido-100 Capsules by M/s Atco Labs, Karachi (Reg#047188)
	GMP status	Last inspection dated 12-01-2018 for grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
346.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Medoxifen 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tamoxifen as Citrate…20mg"
	Diary No. Date of R& I & fee	Dy. No 37188 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Anti-oestrogens
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	TAMOXIFEN TABLETS 20MG by M/s REHMAN MEDICINE COMPANY PESHAWAR (Reg#014978)
	GMP status	Last inspection dated 12-01-2018 for grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
347.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Tenvira 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Entecavir as monohydrate…1mg"
	Diary No. Date of R& I & fee	Dy. No 36311 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bvir 1mg Tablet manufactured by Bosch Pharmaceuticals, Karachi Reg. No. 55639
	GMP status	Last inspection dated 02-08-2018 concluding acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of the Evaluator[II]	In contrary to approved by the reference agencies/authorities wherein the applied formulation is approved as Entecavir "as monohydrate" equal to 1mg, while you have applied for Entecavir monohydrate equal to 1mg. Clarification is required in this regard.
	Decision: Deferred for revision of formulation as per reference product.	
348.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Tenvira 0.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Entecavir as monohydrate…0.5mg"
	Diary No. Date of R& I & fee	Dy. No 36319 dated 01-11-2018 Rs.20,000/- Dated 01-11-2018

	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	20's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bvir 0.5mg Tablet manufactured by Bosch Pharmaceuticals, Karachi Reg. No. 055638
	GMP status	Last inspection dated 02-08-2018 concluding acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of the Evaluator[II]	• In contrary to approved by the reference agencies/authorities wherein the applied formulation is approved as Entecavir "as monohydrate" equal to 0.5mg, while you have applied for Entecavir monohydrate equal to 0.5mg. Clarification is required in this regard.
	Decision: Deferred for revision of formulation as per reference product.	
349.	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	Afino 0.75mg Tablets
	Composition	"Each Tablet Contains: Everolimus……0.75mg"
	Diary No. Date of R& I & fee	Dy. No 36414 dated 05-11-2018 Rs.20,000/- Dated 05-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per latest decision taken by DPC in respect of ususal/hardship cases.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	CERTICAN TABLETS 0.75MG by M/s NOVARTIS PHARMA, Karachi Reg. No. 044830
	GMP status	Last inspection dated 14-06-2018 recommending issuance of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	
350.	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	Afino 0.25mg Tablets
	Composition	"Each Tablet Contains: Everolimus…….0.25mg"
	Diary No. Date of R& I & fee	Dy. No 36413 dated 05-11-2018 Rs.20,000/- Dated 05-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per latest decision taken by DPC in respect of ususal/hardship cases.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	CERTICAN TABLETS 0.25MG by M/s NOVARTIS PHARMA, Karachi Reg. No. 044829
	GMP status	Last inspection dated 14-06-2018 recommending issuance of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	
351.	Name and address of manufacturer /	"M/s Sami Pharmaceuticals Pvt Limited. F-95, S.I.T.E, Karachi,

	Applicant	Pakistan"
	Brand Name +Dosage Form + Strength	Afino 2.5mg Tablets
	Composition	"Each Tablet Contains: Everolimus…….2.5mg"
	Diary No. Date of R& I & fee	Dy. No 37122 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per latest decision taken by DPC in respect of ususal/hardship cases.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	AFINITOR 2.5MG TABLETS by M/s NOVARTIS PHARMA, Karachi (Reg. No. 078105)
	GMP status	Last inspection dated 14-06-2018 recommending issuance of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	
352.	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	Afino 10mg Tablets
	Composition	"Each Tablet Contains: Everolimus…….10mg"
	Diary No. Date of R& I & fee	Dy. No 37124 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per decision taken by DPC in respect of ususal/hardship cases.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	AFINITOR 10MG TABLETS by M/s NOVARTIS PHARMA, Karachi (Reg. No. 069520)
	GMP status	Last inspection dated 14-06-2018 recommending issuance of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	
353.	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	Afino 5mg Tablets
	Composition	"Each Tablet Contains: Everolimus…….5mg"
	Diary No. Date of R& I & fee	Dy. No 37123 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per latest decision taken by DPC in respect of ususal/hardship cases.
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	AFINITOR 5MG TABLETS by M/s NOVARTIS PHARMA, Karachi (Reg. No. 069519)
	GMP status	Last inspection dated 14-06-2018 recommending issuance of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision:Approved with innovator's specifications.	

354.	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"
	Brand Name +Dosage Form + Strength	Evercan 0.75mg Tablet
	Composition	"Each Tablet Contains: Everolimus……0.75mg"
	Diary No. Date of R& I & fee	Dy. No 37121 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	CERTICAN TABLETS 0.75MG by M/s NOVARTIS PHARMA, Karachi Reg. No. 044830
	GMP status	Last inspection dated 29-01-2019concluding overall GMP compliant status.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
355.	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"
	Brand Name +Dosage Form + Strength	Evercan 0.25mg Tablet
	Composition	"Each Tablet Contains: Everolimus…0.25mg"
	Diary No. Date of R& I & fee	Dy. No 37120 dated 09-11-2018 Rs.20,000/- Dated 09-11-2018
	Pharmacological Group	Protein kinase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	CERTICAN TABLETS 0.25MG by M/s NOVARTIS PHARMA, Karachi Reg. No. 044829
	GMP status	Last inspection dated 29-01-2019concluding overall GMP compliant status.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
356.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Mycophen 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Mycophenolate mofetil……500mg"
	Diary No. Date of R& I & fee	Dy. No 36964 dated 08-11-2018 Rs.20,000/- Dated 07-11-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Mycophenolate Mofetil 500 mg film-coated tablets by Morningside Healthcare Ltd, Approved by MHRA
	Me-too status (with strength and dosage form)	Mycophenol 500 mg Tablets by Wellborne Pharmachem and Biologicals, Hattar. Reg. No. 77412
	GMP status	GMP Certificate Issued on 27-08-2018
	Remarks of the Evaluator[II]	
	Decision:Approved.	

357.	Name and address of manufacturer / Applicant	"M/s Bio Mark Pharmaceuticals. Plot No. 527, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Mimpara 30mg Tablet
	Composition	"Each film coated tablet Contains: Cinacalcet as HCL…30mg"
	Diary No. Date of R& I & fee	Dy. No 36967 dated 08-11-2018 Rs.20,000/- Dated 07-11-2018
	Pharmacological Group	Anti-parathyroid agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	--
	GMP status	GMP Certificate Issued on 27-08-2018
	Remarks of the Evaluator[II]	Submit stability data as per format decided by Registration Board in its 278th meeting.
	Decision: Deferred for submission of stability data as per format decided by Registration Board in its 278th meeting.	
358.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Tacrim 1mg Capsule
	Composition	Each Capsule Contains: Tacrolimus as Monohydrate…1mg
	Diary No. Date of R & I & fee	Dy.No 44501 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Inograf 1 mg capsule by Platinum Pharma (Reg.# 045491)
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator[V]	
	Decision:Approved.	
359.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Tacrim 0.5mg Capsule
	Composition	"Each Capsule Contains: Tacrolimus as Monohydrate…0.5mg"
	Diary No. Date of R & I & fee	Dy.No 44502 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Inograf 0.5 mg capsule by Platinum Pharma (Reg.# 045490)
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator[V]	
	Decision:Approved.	

360.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Thalide 50mg Capsule
	Composition	"Each Capsule Contains: Thalidomide…50mg'
	Diary No. Date of R & I & fee	Dy.No 44507 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Thalido 50mg Capsules by M/s Atco (Reg.# 048589)
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator[V]	
	Decision:Approved.	
361.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Suninit 25mg Capsule
	Composition	"Each capsule contains: Sunitnib as Sunitinib malate…25mg"
	Diary No. Date of R & I & fee	Dy. No 44495 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti-cancer
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SUTENT 25MG CAPSULE by M/s Pfizer (Reg.# 052226)
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator[V]	
	Decision: Deferred for Evidence of approval of required manufacturing facility for "Cytotoxic drugs" from CLB.	
362.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Suninit 12.5mg Capsule
	Composition	"Each capsule contains: Sunitnib as Sunitinib malate…12.5mg"
	Diary No. Date of R & I & fee	Dy. No 44496 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti-cancer
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SUTENT 12.5MG CAPSULE by M/s Pfizer (Reg.# 052225)
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator[V]	
	Decision: Deferred for Evidence of approval of required manufacturing facility for "Cytotoxic drugs" from CLB.	

363.	Name and address of manufacturer / Applicant	"M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Suninit 50mg Capsule
	Composition	"Each capsule contains: Sunitnib as Sunitinib malate…50mg"
	Diary No. Date of R & I & fee	Dy.No 40297 dated 31-12-2018 Rs.20,000/- Dated 31-12-2018
	Pharmacological Group	Anti-cancer
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	SUTENT 50MG CAPSULE by M/s Pfizer (Reg.# 052227)
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator[V]	
	Decision: Deferred for Evidence of approval of required manufacturing facility for "Cytotoxic drugs" from CLB.	

b. Availability of Drugs

The Board in its 277th meeting held on 27th - 29th, December, 2017 decided that for the following molecules, which are generally reported to be in short supply and having limited or no manufacturers/importers, the registration application shall have priority review process and consideration by the Board to ensure their free availability.

a. Fludrocortisone 0.1 mg Tablet.
b. Amiodarone 100 & 200 mg Tablets, and 30mg/ml & 50mg/ml Injection.
c. Clobazam 10 mg Tablet.
d. Acetazolamide 250 Tablets.
e. Hydrochlorthiazide 25 mg & 50 mg Tablets.
f. Streptomycin 1 gram Injection.
g. Nitrofurantoin 50 mg & 100 mg Tablet.

Accordingly in 287th meeting of Registration Board the relevant applications from available record were presented. Now following applications of above cited formulations have been identified in record and are presented here for consideration of Board:

364.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Actaglucom 250mg Tablet
	Composition	"Each Tablet Contains: Acetazolamide……250mg"
	Diary No. Date of R& I & fee	Dy. No 21654 dated 20-06-2018 Rs.20,000/- Dated 20-06-2018
	Pharmacological Group	Carbonic anhydrase 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.	Approved by MHRA of UK
	Me-too status	Acetamide Tablets of M/s Werrick Pharma. (Reg.#025175)
	GMP status	GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator[2]	
	Decision: Approved.	
365.	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	Acetamid Tablets 250mg

	Composition	"Each tablet contains: Acetazolamide……250mg"
	Diary No. Date of R& I & fee	Dy. No 8774 dated 27-02-2019 Rs.20,000/- Dated 26-02-2019
	Pharmacological Group	Carbonic anhydrase inhibitor
	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.	Approved by MHRA of UK
	Me-too status	Acetamide Tablets of M/s Werrick Pharma. (Reg.#025175)
	GMP status	13-07-2017 for Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator[2]	
	Decision: Approved.	
366.	Name and address of manufacturer / Applicant	"M/s Sante Pvt Ltd A-97, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Tazol 250mg Tablet
	Composition	"Each Tablet Contains: Acetazolamide…250mg"
	Diary No. Date of R& I & fee	Dy. No 1675 dated 14-01-2019 Rs.20,000/- Dated 14-01-2019
	Pharmacological Group	Carbonic anhydrase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	100's; MRP Rs. 750/- 30's; MRP Rs. 350/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Acetamide Tablets of M/s Werrick Pharma. (Reg.#025175)
	GMP status	Last inspection report dated 29-3-17 confirms satisfactory compliance to GMP
	Remarks of the Evaluator[2]	
	Decision: Approved.	
367.	Name and address of manufacturer / Applicant	"M/s Ameer & Adnan Pharmaceuticals Pvt. Limited, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahore."
	Brand Name +Dosage Form + Strength	Amedone 3ml injection
	Composition	Each 3ml contains: Amiodarone hydrochloride …… 150mg
	Diary No. Date of R& I & fee	Dy. No 7064 dated 19-02-2019 Rs. 20,000 Dated 19-02-2019
	Pharmacological Group	Antiarrhythmic
	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	Cordaronex I.V Injection of M/s Khalid Brothers, Karachi (Reg.# 010645)
	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[2]	
	Decision: Approved.	
368.	Name and address of manufacturer / Applicant	"M/s Ameer & Adnan Pharmaceuticals Pvt. Limited, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahore."
	Brand Name +Dosage Form + Strength	Amedone 100mg tablets
	Composition	Each tablet contains: Amiodarone hydrochloride …… 100mg
	Diary No. Date of R& I & fee	Dy. No 13498 dated 11-04-2018 Rs. 20,000 Dated 11-04-2018
	Pharmacological Group	Antiarrhythmic

	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Amid Tablets of M/s. C.C.L Pharmaceuticals, (Pvt) Ltd (Reg.# 045973)
	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[2]	
	Decision: Approved.	
369.	Name and address of manufacturer / Applicant	"M/s Bajwa Pharmaceuticals (Pvt) Ltd. 36-Km, GT Road Khori Murredke, Sheikhupura"
	Brand Name +Dosage Form + Strength	Amiodarone HCl Injection 150mg/3ml
	Composition	"Each ml contains: Amiodarone HCl …50mg"
	Diary No. Date of R& I & fee	Dy. No 7987 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Antiarrhythmic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3ml ampoule; As PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Cordaronex I.V Injection of M/s Khalid Brothers, Karachi (Reg.# 010645)
	GMP status	Last GMP inspection was conducted on 21-02-2018 and the report concludes as under: "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[2]	
	Decision: Approved.	
370.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Fribium 10mg Tablet
	Composition	"Each Tablet Contains: Clobazam ……10mg"
	Diary No. Date of R& I & fee	Dy. No 7987 dated 22-02-2019 Rs.20,000/- Dated 22-02-2019
	Pharmacological Group	Benzodiazepine
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Frisium tablet of M/s Sanofi-Aventis (Reg.# 002694)
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator[2]	
	Decision: Deferred for evidence of approval of required manufacturing facility of "Tablet (Psychotropic) Section" from CLB.	
371.	Name and address of manufacturer / Applicant	"M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Fludrocort 0.1mg Tablet
	Composition	"Each Tablet Contains: Fludrocortisone Acetate…0.1mg"
	Diary No. Date of R& I & fee	Dy. No 44230 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Mineralocorticoid

	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 6.25mg per tablet Rs. 125mg per 20's
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	--
	GMP status	Last inspection report 07-02-2018 concluding as under: On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection
	Remarks of the Evaluator[2]	• Evidence of required manufacturing facility required. • Evidence of me-too status required.
	Decision: Deferred for following: • **Evidence of approval of required manufacturing facility for applied formulation from CLB.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
372.	Name and address of manufacturer / Applicant	"M/s Ameer & Adnan Pharmaceuticals Pvt. Limited, Plot No. 47, Sunder Industrial Estate, Raiwind Road, Lahore."
	Brand Name +Dosage Form + Strength	Amedone 200mg tablets
	Composition	Each tablet contains: Amiodarone hydrochloride …… 200mg
	Diary No. Date of R& I & fee	Dy. No 7899 dated 22-02-2019 Rs. 20,000 Dated 11-04-2018
	Pharmacological Group	Antiarrhythmic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Amid Tablets of M/s. C.C.L Pharmaceuticals, (Pvt) Ltd (Reg.# 045972)
	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[2]	
	Decision: Approved.	

c. Export Facilitation.

Assistant Director (Reg-II) vide letter no. F.5-85/2013-Reg-V (Vol-I) dated 25-02-2019, has declared that M/s CCL Pharmaceutical (Pvt.) Ltd, Lahore has claimed for export of USD 40,20,355/- during the fiscal year 2017-18, achieved the benchmark as defined in the Board's decision. The firm has requested for priority evaluation/consideration of their following applications.

373.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Xalia 2.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rivaroxaban…….2.5mg"
	Diary No. Date of R& I & fee	Dy. No 27394 dated 09-08-2018 Rs.20,000/- Dated 09-08-2018
	Pharmacological Group	Antithrombic agent
	Type of Form	Form-5
	Finished product Specifications	Innovator's specification
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Xarelto of M/s Bayer healthcare approved by EMA
	Me-too status (with strength and dosage form)	Xarelto 2.5mg Tablet by M/s. Bayer Pakistan (private) limited (Reg#074794)
	GMP status	Firm has submitted copy of GMP inspection report conducted on

		08-03-2017 & 31-03-2017, concluding the firm was found to be operating at satisfactory level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	
374.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Doxyline Capsule 50mg
	Composition	"Each capsule contains: Doxycycline Hyclate eq. to Doxycyxline……50mg"
	Diary No. Date of R& I & fee	Dy. No 204 dated 02-01-2019 Rs.20,000/- Dated 02-01-2019
	Pharmacological Group	Tetracycline
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Doxinom-50 Capsules by M/s. Genome Pharmaceuticals (Pvt.) Ltd (Reg#060832)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision: Approved.	
375.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Doxyline Capsule 100mg
	Composition	"Each capsule contains: Doxycycline Hyclate eq. to Doxycyxline……100mg"
	Diary No. Date of R& I & fee	Dy. No 205 dated 02-01-2019 Rs.20,000/- Dated 02-01-2019
	Pharmacological Group	Tetracycline
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Doxinom-100 Capsules by M/s. Genome Pharmaceuticals (Pvt.) Ltd (Reg#056095)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
376.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Vcon Tablet 200mg
	Composition	"Each film coated tablet contains: Voriconazole……200mg"
	Diary No. Date of R& I & fee	Dy. No 202 dated 02-01-2019 Rs.20,000/- Dated 02-01-2019
	Pharmacological Group	Anti-mycotic
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Vorinaz Tablet by M/s Atco Lab. Karachi (Reg.# 081097)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	

377.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Qutyl XR 300mg Tablet
	Composition	"Each Extended Release Film Coated Tablet Contains: Quetiapine Fumarate Eq. to Quetiapine…300mg"
	Diary No. Date of R& I & fee	Dy. No 14481 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-psychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Quit XR 300 mg Tablets by M/s. Navegal Laboratories (Reg.# 078467)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
378.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Qutyl XR 200mg Tablet
	Composition	"Each Extended Release Film Coated Tablet Contains: Quetiapine Fumarate Eq. to Quetiapine…200mg"
	Diary No. Date of R& I & fee	Dy. No 14480 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-psychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Pine XR Tablet by M/s. Werrick Pharmaceuticals (Reg.# 082047)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
379.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate,Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Qutyl XR 150mg Tablet
	Composition	"Each Extended Release Film Coated Tablet Contains: Quetiapine Fumarate Eq. to Quetiapine…150mg"
	Diary No. Date of R& I & fee	Dy. No 14479 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-psychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per brand leader
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA
	Me-too status (with strength and dosage form)	Qusel XR 150mg tablet of M. Ray Pharma (Reg.#067501)
	GMP status	As recorded for above application
	Remarks of the Evaluator[II]	
	Decision:Approved.	
380.	Name and address of Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore."
	Detail of Drug Sale License	N/A
	Name and address of manufacturer	M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP,

	Thuan An District, Binh Duong, Vietnam
Name and address of marketing authorization holder	M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam. Number of product license and date of issue: VD-30864-18 dated 05th July, 2018.
Name of exporting country	Vietnam
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No 35872 Dated 29-10-2018
Fee including differential fee	Rs. 100,000/- Dated 29-10-2018
Brand Name +Dosage Form + Strength	Isotret 10mg Soft Gelatin capsule
Composition	"Each softgel capsule contains: Isotretinoin…….10mg"
Finished Product Specification	Manufacturer specifications.
Pharmacological Group	Retinoic for treatment of acne
Shelf life	3 years
Demanded Price	As per brand leader
Pack size	
International availability	Approved by USFDA
Me-too status	Acnotin 10 Soft Gelatin Capsules of M/s Ferozsons Laboratories Ltd, (Reg.# 070318)
Stability studies	• Long term stability studies of 36 months and Accelerated stability studies of 6 months of three batches at Zone-IV A conditions.
Detail of certificates attached	• Original Legalized Free Sale certificate issued by Ministry of Health Vietnam, Drug Administration valid upto 05-07-2023. • Original Legalized CoPP (Certificate#. 692/GP-QLP) issued on 14-08-2018 by Ministry of Health Vietnam, Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam • Legalized copy of GMP certificate issued by Ministry of Health Vietnam, Drug Administration, in the name of M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam valid for three years from date of approval. • Copy of "Letter of Authorization" from M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam authorising M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore to carry out registration process in Pakistan for applied product.

Remarks of the Evaluator:

Sr. #	Observations (Communicated vide letter No. F.1-1/2017/PEC-DRAP (AD PEC-II dated 11-04-2019))	Response of Firm (Received vide letter No. CCL/19/R-242 dated 06-05-2019)
i.	Clarification shall be submitted whether application is for "Finished pharmaceutical product import" or "Bulk import and local repack", since it is not evident form the submitted Form-5A.	Firm has submitted revised Form 5-A with following details: **Name and address of the indenter or agent:** "M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore." **Name and address of the manufacturer of drug:** "M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8,

			VSIP, Thuan An District, Binh Duong, Vietnam" **Bulk Import and local repack at:** M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore. • The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam. • The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore
	i.	Manufacturer has referred finished product specifications as in-house, whereas USP and BP monograph is available for applied formulation. Clarification shall be submitted in this regard	Revised technical specifications of finished product have been submitted as per USP monograph for the Isotretinoin capsules. This revised document does not have any signatures or revision/effective date.
	i.	Finished product specifications submitted from manufacturer of applied formulation does not contain dissolution test. Clarification/Justification shall be submitted in this regard.	Revised finished product testing method has been submitted wherein dissolution test as per USP test 2 from USP monograph for the Isotretinoin capsules has been mentioned.
	.	Dissolution test has not been performed during the stability studies. Clarification/justification shall be submitted in this regard.	Revised stability study reports have been submitted for three batches as per Zone IV-b conditions wherein dissolution test and its results have been mentioned • It is pertinent to mention that revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.

• Submitted data of stability studies submitted from manufacturer reveal that stability has been performed with packaging of 1000 capsules per aluminium poly bag-bulk packaging.

Decision: Deferred for following observations:

- **The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam.**
- **The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore.**
- **Revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.**

381.	Name and address of Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore
	Detail of Drug Sale License	N/A
	Name and address of manufacturer	M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam
	Name and address of marketing authorization holder	M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam. Number of product license and date of issue: VD-30864-18 dated 05th July, 2018.

Name of exporting country	Vietnam
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No 35873 Dated 29-10-2018
Fee including differential fee	Rs. 100,000/- Dated 29-10-2018
Brand Name +Dosage Form + Strength	Isotret 20mg Soft Gelatin capsule
Composition	"Each softgel capsule contains: Isotretinoin…….20mg"
Finished Product Specification	Manufacturer specifications.
Pharmacological Group	Retinoic for treatment of acne
Shelf life	3 years
Demanded Price	
Pack size	As per brand leader
International availability	Approved by USFDA
Me-too status	Acnotin 20 Soft Gelatin Capsules of M/s Ferozsons Laboratories Ltd, (Reg.# 070319)
Stability studies	• Long term stability studies of 36 months and Accelerated stability studies of 6 months of three batches at Zone-IV A conditions.
Detail of certificates attached	• **Original Legalized Free Sale certificate** issued by Ministry of Health Vietnam, Drug Administration valid upto 05-07-2023. • **Original Legalized CoPP (Certificate#. 692/GP-QLP)** issued on 14-08-2018 by Ministry of Health Vietnam, Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam • **Legalized copy of GMP certificate** issued by Ministry of Health Vietnam, Drug Administration, in the name of M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam valid for three years from date of approval. • **Copy of "Letter of Authorization" from** M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam authorising M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore to carry out registration process in Pakistan for applied product.

Remarks of the Evaluator:

Sr. #	Observations (Communicated vide letter No. F.1-1/2017/PEC-DRAP (AD PEC-II dated 11-04-2019))	Response of Firm (Received vide letter No. CCL/19/R-242 dated 06-05-2019)
i.	Clarification shall be submitted whether application is for "Finished pharmaceutical product import" or "Bulk import and local repack", since it is not evident form the submitted Form-5A.	Firm has submitted revised Form 5-A with following details: **Name and address of the indenter or agent:** "M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore." **Name and address of the manufacturer of drug:** "M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam" **Bulk Import and local repack at:** M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore. • The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh

			Duong, Vietnam. • The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore
	i.	Manufacturer has referred finished product specifications as in-house, whereas USP and BP monograph is available for applied formulation. Clarification shall be submitted in this regard	Revised technical specifications of finished product have been submitted as per USP monograph for the Isotretinoin capsules. This revised document does not have any signatures or revision/effective date.
	i.	Finished product specifications submitted from manufacturer of applied formulation does not contain dissolution test. Clarification/Justification shall be submitted in this regard.	Revised finished product testing method has been submitted wherein dissolution test as per USP test 2 from USP monograph for the Isotretinoin capsules has been mentioned.
	.	Dissolution test has not been performed during the stability studies. Clarification/justification shall be submitted in this regard.	Revised stability study reports have been submitted for three batches as per Zone IV-b conditions wherein dissolution test and its results have been mentioned • It is pertinent to mention that revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.

• Submitted data of stability studies submitted from manufacturer reveal that stability has been performed with packaging of 1000 capsules per aluminium poly bag-bulk packaging.

Decision: Deferred for following observations:

• **The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam.**

• **The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore.**

• **Revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.**

Assistant Director (Reg-V) vide letter dated 08-01-2019, has declared that M/s Schazoo Zaka Pvt. Ltd. Sheikhupura has claimed for 3 molecules to be considered on priority against USD 327564/- during the fiscal year July 2017-June 2018, duly verified from submitted documents (Form E GD) as per decision of Registration Board.

382.	Name and address of manufacturer / Applicant	M/s Schazoo Zaka Pvt. Ltd. Sheikhupura
	Brand Name +Dosage Form + Strength	Alerda-D tablets
	Composition	"Each Film Coated Tablet Contains: Desloratadine……5mg"
	Diary No. Date of R& I & fee	Dy. No 16927 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-allergic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Rs. 13 per tablet
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Desdine 5mg Tablet of M/s M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080821)
	GMP status	GMP Certificate issued on the basis of inspection dated 26-06-2018 & 27-06-2018 with following sections: 1- Tablet (Gen, Anti TB) 2- Capsule (Gen) 3- Dry Powder suspension (Gen, Anti TB) 4- Sachet (Gen, Anti TB).
	Remarks of the Evaluator[II]	Firm has requested to consider the above applied product in replacement of their previously submitted application of Roflumilast molecule since stability data is required for that.
	Decision:Approved.	

d. Import Applications of Priority Categories Defined by Registration Board in 257th meeting.

i. Human

383.	**Name and address of Applicant**	M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Detail of Drug Sale License	Address: M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan Validity: 22-06-2019 Status: License to sell drugs by way of "Whole Sale"
	Name and address of manufacturer	M/s CENEXI, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France
	Name and address of marketing authorization holder	M/s Stragen Nordic A/S HelsingØrsgade 8C, HillerØd, Denmark
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 30408 Dated 10-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-09-2018
	Brand Name +Dosage Form + Strength	Urapidil Stragen I.V 50mg/10ml (Solution for Injection)
	Composition	Each 10ml contains: Urapidil ……. 10mg
	Finished Product Specification	USP
	Pharmacological Group	Alpha-adrenoceptor antagonist
	Shelf life	18 months
	Demanded Price	Rs. 8,000/- per 5's
	Pack size	5 ampoules
	International availability	Approved by ANSM of France
	Me-too status	N/A
	Detail of certificates attached	• Original Legalized CoPP Certificate No: 2286/1 Certifying Authority: District Government of Cologne, Deaprtment 24, Zeughausstrae 2-10, 50667 Cologne. (The name of issuing authority is included in the WHO list of "Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce" https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/contacts/en/index1.html as accessed on 19-12-2018) Issue Date: 10-07-2018 Free sale in exporting country: Yes

		Applicant of certificate: M/s Stragen Pharma GmbH, Technologie Park Koln, eupener Strasse 135-137, 50933, Cologne, Germany. • GMP: No • Applicant of certificate: M/s Stragen Pharma GmbH, technologie Park Koln, Eupener Strasse 135-137, 50933, Cologne, Germany • Original legalized GMP Certificate Certificate no. HPF/FR/168/2017 valid upto 22-03-2020 Manufacturer Address: M/s CENEXI – Fontenay Sous Bois, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France Issued by French National Agency for Medicines and Health Products Safety.
	Remarks of the Evaluator: • Firm has submitted an Original legalized statement from M/s Stragen Pharma SA, Switzerland declaring M/s Stragen Nordic A/S Denmark (Product License Holder) an affiliate of M/s Stragen Pharma SA, Switzerland. The statement further grants the M/s Pharmatech Pakistan (Pvt.) Ltd, right to register and to commercialize, the finished product in Pakistan under Stragen Pharma's trademark. • Copy of "License and Supply Agreement" has been submitted between the applicant and M/s Stargen Pharma S.A., Switzerland. • Applicant for COPP is different from Product License Holder. • Only Long term stabilities data for three batches as per Zone IV-A conditions have been submitted by applying bracketing principle on 5ml & 20 ml ampoule	
	Decision: Registration Board deferred the case for evaluation of bracketing principle applied by the firm on "long term stabilities data" in view of applicable ICH guidelines and presentation of complete details before the Board.	
384.	Name and address of Applicant	M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Detail of Drug Sale License	Address: M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan Validity: 22-06-2019 Status: License to sell drugs by way of "Whole Sale"
	Name and address of manufacturer	M/s CENEXI, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France
	Name and address of marketing authorization holder	M/s Stragen Nordic A/S HelsingØrsgade 8C, HillerØd, Denmark
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 30409 Dated 10-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-09-2018
	Brand Name +Dosage Form + Strength	Urapidil Stragen I.V 25mg/5ml (Solution for Injection)
	Composition	Each 5ml contains: Urapidil ……. 25mg
	Finished Product Specification	USP
	Pharmacological Group	Alpha-adrenoceptor antagonist
	Shelf life	18 months
	Demanded Price	Rs. 4,000/- per 5's
	Pack size	5 ampoules
	International availability	Approved by ANSM of France
	Me-too status	N/A
	Detail of certificates attached	• Original Legalized CoPP Certificate No: 2286/2 Certifying Authority: District Government of Cologne, Deaprtment 24, Zeughausstrae 2-10, 50667 Cologne. (The name

		of issuing authority is included in the WHO list of "Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce" https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/contacts/en/index1.html as accessed on 19-12-2018) Issue Date: 10-07-2018 Free sale in exporting country: Yes • GMP: No • Applicant of certificate: M/s Stragen Pharma GmbH, technologie Park Koln, Eupener Strasse 135-137, 50933, Cologne, Germany • Original legalized GMP Certificate Certificate no. HPF/FR/168/2017 valid upto 22-03-2020 Manufacturer Address: M/s CENEXI – Fontenay Sous Bois, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France Issued by French National Agency for Medicines and Health Products Safety.
	Remarks of the Evaluator: • Firm has submitted a Original legalized statement from M/s Stragen Pharma SA, Switzerland declaring M/s Stragen Nordic A/S Denmark (Product License Holder) an affiliate of M/s Stragen Pharma SA, Switzerland. The statement further grants the M/s Pharmatech Pakistan (Pvt.) Ltd, right to register and to commercialize, the finished product in Pakistan under Stragen Pharma's trademark. • Applicant for COPP is different from Product License Holder. • Only Long term stabilities data for three batches as per Zone IV-A conditions have been submitted by applying bracketing principle on 5ml & 20 ml ampoule.	
	Decision: Registration Board deferred the case for evaluation of bracketing principle applied by the firm on "long term stabilities data" in view of applicable ICH guidelines and presentation of complete details before the Board.	
385.	Name and address of Applicant	"M/s RG Pharmaceuticals Pvt Ltd. 703, Progressive Square, P.EC.H.S., Block-6, Shahrah-e-Faisal, Karachi, Pakistan
	Detail of Drug Sale License	Address: M/s RG Pharmaceutica Pvt Ltd. 703, Progressive Square, P.EC.H.S., Block-6, Shahrah-e-Faisal, Karachi, Pakistan Validity: 17-01-2021 Status: Drug License by way of WholeSale.
	Name and address of manufacturer	M/s Hanlim Pharm. Co., Ltd. 2-27, Yeongmun-Ro, Cheoin-Gu, Yongin-Si, Gyeonggi-do, Republic of Korea"
	Name and address of marketing authorization holder	M/s Hanlim Pharm. Co., Ltd. 2-27, Yeongmun-Ro, Cheoin-Gu, Yongin-Si, Gyeonggi-do, Republic of Korea"
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 32990 Dated 03-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 03-10-2018
	Brand Name+Dosage Form+Strength	Carbella 0.01% Solution for Injection
	Composition	"Each ml Contains: Carbetocin…….100µg"
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Oxytocin & analogue (indicated for the prevention of uterine atony following delivery of the infant by Caesarean section under epidural or spinal anaesthesia)
	Shelf life	36 months: Store in a refrigerator 2°C to 8°C.
	Demanded Price	
	Pack size	1ml glass ampoule x 5's

	International availability	PABAL 100 micrograms/ml solution for injection of M/s Ferring Pharmaceuticals Ltd. approved by MHRA of UK.
	Me-too status	N/A
	Stability studies	Firm has submitted long term (36 months) at $2^{o}C$ - $8^{o}C$ & accelerated (06 months) stability data at 25± $2^{o}C$, 60± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018-D1-1220)** issued on 29-05-2018 by Gyeongin Regional Food and Drug Administration, Korea, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Hanlim Pharm. Co., Ltd. 2-27, Yeongmun-Ro, Cheoin-Gu, Yongin-Si, Gyeonggi-do, Republic of Korea. • **Original legalized GMP certificate** issued by Commissioner ofGyeongin Regional office of Food and Drug Safety for the M/s Hanlim Pharm. Co., Ltd. 2-27, Yeongmun-Ro, Cheoin-Gu, Yongin-Si, Gyeonggi-do, Republic of Korea, valid till 18-12-2019. • **Original Notarized "Letter of Authorization" from** M/s Hanlim Pharm. Co., Ltd. 2-27, Yeongmun-Ro, Cheoin-Gu, Yongin-Si, Gyeonggi-do, Republic of Korea declaring M/s RG Pharmaceutica Pvt Ltd. 703, Progressive Square, P.EC.H.S., Block-6, Shahrah-e-Faisal, Karachi, Pakistan as sole and exclusive distributor of applied product in aterritory defined as Pakistan.
	Remarks of the Evaluator.	• The application has been forwarded by Dir. Biological Drugs, vide letter no. F.3-54/2017-AD (BD)EVN/RG dated 30-10-2018, stating as under: "During evaluation, it is observed that the active substance Carbetocin is a synthetic analogue and not a biological substance. MHRA assessment report of Pabal 100 µg/ml (Carbetocin) clearly indicates that the Carbetocin is a synthetic analogue and manufactured by synthetic method."
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	
386.	Name and address of Applicant	"M/s Punjab Medical Services, Office No: 4/5 2, Floor jala Center Opp, OPC Gate Gangaram Hospital Mozang Road Lahore.
	Detail of Drug Sale License	Address: M/s Punjab medical Services Pharmacy, Sharif mansion near ganga ram Hospital, 16-Queens Road Lahore License no.: 05-352-0063-01231P Validity: 09-08-2019 Status: License to sell Drugs in a Pharmacy.
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Gebze Organize Sanayi Bolgesi, 1700 sokak, No:1703,Gebze Kocaeli, Turkey
	Name and address of marketing authorization holder	M/s Onko Ilac Sanayi ve Tic A.S kosuyolu cad No: 34, 34718 Kosuyolu kadikoy, Istanbul, Turkey.
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 38774 Dated 26-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 26-11-2018
	Brand Name +Dosage Form + Strength	Exetu 25mg film coated tablets
	Composition	"Each film coated tablet contains: Exemestane..... 25mg"
	Finished Product Specification	Manufacturer's specifications
	Pharmacological Group	Anti-neoplastic agents. ATC code: L02BG06
	Shelf life	36 months

	Demanded Price	As per SRO
	Pack size	--
	International availability	Approved by EMA (European Medicine Agency)
	Me-too status	N/A
	Stability studies	Firm has submitted long term (36 months) at 30± 2°C, 65± 5% RH & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate no.: 2018/1248)** issued on 27-03-2018 by Ministry of Healthy Turkish Medicines and Medical Devices Agency, declaring the free sale of applied product in the exporting country i.e., Turkey and the GMP compliant status of the manufacturer. • **Original Legalized GMP certificate** (Certificate# TR/GMP/2017/188) issued by Ministry of Healthy Turkish Medicines and Medical Devices Agency in the name of M/s Onko Ilac Sanayi ve Tic A.S kosuyolu cad No: 34, 34718 Kosuyolu kadikoy, Istanbul, Turkey. valid upto May, 2019. • Copy of "Letter of Authorization" by Onko İlaç Sanayi ve Ticaret A.Ş located at Koşuyolu Cad. No: 34, 34718, Kadiköy Istanbul, Turkey, issued in the name of M/s Punjab medical Services on 22-03-2018 and valid for 3 years is submitted by the firm.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	

Case No. 05: Registration Applications of Import Cases.

a. New Cases (Veterinary)

387.	Name and address of Applicant	"M/s Samara Store, C-140, Block-D, Unit # 6, Latifabad, Hyderabad, Pakistan"
	Detail of Drug Sale License	Address: M/s Samara Medical Store, Shop No. 17 Qamar Market Unit No. 07 Latifabad, Hyderabad. Validity: 26-03-2020 Status: License to sell, stock and exhibition for sale, distribute drugs by way of retail sale.
	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan Registration No. 42/5/2005 Registration date: 16/06/2005 Re-Registration date: 27-08-2015dated 13-09-1996
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No10671 Dated 23-03-2018
	Fee including differential fee	Rs. 50,000/- Dated 22-03-2018 Rs. 50,000/- Dated 15-04-2019
	Brand Name +Dosage Form + Strength	Tilmotil oral solution
	Composition	Each 1ml contains: Tilmicosin (as Tlimicosin phospahte) ……. 250mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Antibiotic

	Shelf life	36 months if stored at a temperature below 30°C
	Demanded Price	De-controlled
	Pack size	120ml & 240ml.
	International availability	Not applicable
	Me-too status	Tilcosin Solution of M/s Selmore Pharmaceuticals (PVT) LTD., Lahore. (Reg.# 035150)
	Stability studies	Firm has submitted long term (36 months) accelerated (06 months) stability data for three batches as per Zone IV-a conditions.
	Detail of certificates attached	• **Original& Legalized Certificate issued** by Minister of Agriculture & Minister of Environment, (Ministry of Agriculture/Veterinary Department) issued on 27-03-2019 declaring that applied product is produced by M/s The Arab Pesticides & Veterinary Drugs Mfg. Co. under the same name, composition and pack and is used at the country of origin (Jordan), • **Original & Legalized GMP certificate (004287)** issued byMinister of Agriculture in the name of M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan, valid for three years from date of issue i.e., 27-03-2019. • Copy of Exclusive agency agreement has been submitted.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	
388.	Name and address of Applicant	"M/s Samara Store, C-140, Block-D, Unit # 6, Latifabad, Hyderabad, Pakistan"
	Detail of Drug Sale License	Address: M/s Samara Medical Store, Shop No. 17 Qamar Market Unit No. 07 Latifabad, Hyderabad. Validity: 26-03-2020 Status: License to sell, stock and exhibition for sale, distribute drugs by way of retail sale.
	Name and address of manufacturer	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan
	Name and address of marketing authorization holder	M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan Registration No. 42/5/2005 Registration date: 16/06/2005 Re-Registration date: 27-08-2015dated 13-09-1996
	Name of exporting country	Jordan
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No10672 Dated 23-03-2018
	Fee including differential fee	Rs. 50,000/- Dated 22-03-2018 Rs. 50,000/- Dated 15-04-2019
	Brand Name +Dosage Form + Strength	Colivet 4.8 water soluble powder
	Composition	Each 1gm contains: Colistin sulphate …… 4.8 mIU
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Antibiotic
	Shelf life	36 months if stored at a temperature below 30°C
	Demanded Price	De-controlled
	Pack size	100gm, 500gm, 1Kg
	International availability	Not applicable
	Me-too status	COLAK POWDER of M/s A & K Pharmaceutical Faisalabad (Reg.# 049796)

	Stability studies	Firm has submitted long term (36 months) accelerated (06 months) stability data for three batches as per Zone IV-a conditions.
	Detail of certificates attached	• **Original& Legalized Certificate issued** by Minister of Agriculture & Minister of Environment, (Ministry of Agriculture/Veterinary Department) issued on 27-03-2019 declaring that applied product is produced by M/s The Arab Pesticides & Veterinary Drugs Mfg. Co. under the same name, composition and pack and is used at the country of origin (Jordan), • **Original & Legalized GMP certificate (004287)** issued byMinister of Agriculture in the name of M/s The Arab Pecticides & Veterinary Drugs Mfg. Co. Factory/El-Hassan Industrial Estate-Ibrid, Jordan, valid for three years from date of issue i.e., 27-03-2019. • Copy of Exclusive agency agreement has been submitted.
	Remarks of the Evaluator.	• Notarized Copy of Exclusive agency agreementt shall be submitted.
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	

b. Deferred Cases.

i. Human.

389.	Name and address of Applicant	M/s Fabnos International 26-C, Tauheed commercial area, street No. 26 Phase V, DHA Karachi
	Detail of Drug Sale License	Address: Fabnos International, 26/C, Ist floor, Tauheed Comm, Area, 26th street Phase V, Karachi Validity: 01-06-2020 Status: Drug License by way of WholeSale.
	Name and address of manufacturer	M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia, Carrera 53N 50-09, Autopista Medellin-Bogota kilometro 22 Guarne Antioquia, Colombia, South America
	Name and address of marketing authorization holder	M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia"
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 27 Dated 11-12-2007
	Fee including differential fee	Rs. 15,000/- Dated 10-12-2007 Rs. 85000/- Dated 30-04-14
	Brand Name +Dosage Form + Strength	Lidocaine 2%
	Composition	Each dental cartridge of 1.8ml contains: Lidocaine hydrochloride …… 36mg
	Finished Product Specification	USP
	Pharmacological Group	Anaesthetic
	Shelf life	2 years
	Demanded Price & Pack size	14$ per cartridge/ Glass cartridge of 1.8ml
	International availability	--
	Me-too status	--
	Previous remarks of evaluator	• International availability not confirmed. • Me-too status not confirmed • Legalized COPP need to be submitted, Firm has submitted copy of COPP.

	Previous decision	Registration board in its 254th meeting Deferred for: • Submission of Legalized COPP. • Confirmation of availability in reference drug authorities. • Confirmation of me-too status. • Stability studies as per ICH/WHO Zone IV-A conditions.
	Evaluation by PEC	Firm Has Submitted Following: • Legalized Copy Of "COPP" Both In Spanish And With English Translation (Certificate# 2018005595) Issued By "National Institute For The Surveillance Of Medications And Foods", Ministry Of Health And Social Protection, Republic Of Colombia. • Following Particulars Are Evident Form The Submitted Copp: ➢ Free Sale Status In The Exporting Country I.E., Colombia: Available ➢ Market Authorization Holder: "M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia" ➢ Product Authorization Number: INVIMA 2012m-004009 R4 ➢ Manufcaturer: M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia ➢ GMP status of manufacturer: Compliant ➢ Issue don: 10-04-2018 • Long term (36 months) & accelerated (06 months) stability studies data has been submitted for three batches as per Zone-IV b conditions.
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
390.	Name and address of Applicant	M/s Fabnos International 26-C, Tauheed commercial area, street No. 26 Phase V, DHA Karachi
	Detail of Drug Sale License	Address: Fabnos International, 26/C, Ist floor, Tauheed Comm, Area, 26th street Phase V, Karachi Validity: 01-06-2020 Status: Drug License by way of WholeSale.
	Name and address of manufacturer	M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia
	Name and address of marketing authorization holder	M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia"
	Name of exporting country	Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26 Dated 11-12-2007
	Fee including differential fee	Rs. 15,000/- Dated 10-12-2007 Rs. 85000/- Dated 30-04-14
	Brand Name +Dosage Form + Strength	Lidocaine 2% E80
	Composition	Each dental cartridge of 1.8ml contains: Lidocaine ashydrochloride……36mg Epinephrine….0.2250mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Anaesthetic
	Shelf life	2 years
	Demanded Price & Pack size	14$ per cartridge/ Glass cartridge of 1.8ml
	International availability	--
	Me-too status	--

	Previous remarks of evaluator	• International availability not confirmed. • Me-too status not confirmed • Legalized COPP need to be submitted, Firm has submitted copy of COPP.
	Previous decision	Registration board in its 254th meeting Deferred for: • Submission of Legalized COPP. • Confirmation of availability in reference drug authorities. • Confirmation of me-too status. • Stability studies as per ICH/WHO Zone IV-A conditions.
	Evaluation by PEC	Firm Has Submitted Following: • Legalized Copy Of "COPP" Both In Spanish And With English Translation (Certificate# 2018005596) Issued By "National Institute For The Surveillance Of Medications And Foods", Ministry Of Health And Social Protection, Republic Of Colombia. • Following Particulars Are Evident Form The Submitted Copp: ➢ Free Sale Status In The Exporting Country I.E., Colombia: Available ➢ Market Authorization Holder: "M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia" ➢ Product Authorization Number: INVIMA 2012m-004009 R4 ➢ Manufcaturer: M/s Productora Y Comercializadora Odontologica New Stetic S.A., Guarine, Antioquia ➢ GMP status of manufacturer: Compliant ➢ Issue don: 10-04-2018 • Long term (36 months) & accelerated (06 months) stability studies data has been submitted for three batches as per Zone-IV b conditions.
	Decision: Deferred for clarification of applied composition, since reference product contains "Lidocaine hydrochloride ….. 36 mg" whereas applied product conatins "Lidocaine as hydrochloride…..36mg."	
391.	Name and address of Applicant	M/s Medinet Pharmaceuticals ,Building No. 601, First Floor , Main Peshawar Road, Near Lane No. 5, Rawalpindi
	Detail of Drug Sale License	Address: Building No. 601, First Floor , Main Peshawar Road, Near Lane No. 5, Rawalpindi Validity: 16-02-2018 Status: License to sell drugs as a distributor
	Name and address of manufacturer	Biomendi , S. A.U , Poligono Industrial de Bernedo ,s/n, 01118, Bernedo (Alava), Spain
	Name and address of marketing authorization holder	License Holder/MAH G.E.S Genericos Espanoles Laboratorio, S. A. Colquide 6-Portal 2,1 –Oficina F 28230 Las Rozas Madrid Spain Product Owner M/s Altan Pharma Limited , 2 Harbour Square, Crofton Road Dun Laoghair , Co. Dublin, Ireland Tha Altan Pharma Limited is the ultimate shareholder of its affiliate G.E.S Genericos Espanoles Laboratorio and Biomendi , S. A.
	Name of exporting country	Spain
	Type of Form	Form 5-A

	Diary No. & Date of R& I	Dy. No. 3465 Dated 26/1/2018
	Fee including differential fee	Rs. 100,000/- Dated 26/1/2018
	Brand Name +Dosage Form + Strength	Thrombostat Injection 12.5mg/250mg Solution for Infusion
	Composition	One bag of thrombostat contains: Tirofiban 12.5mg/250ml
	Finished Product Specification	Inhouse
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin ATC Code: B01AC17
	Shelf life	2 years
	Demanded Price & Pack size	Rs 18,934.75; Bag of PVC free polyolefin
	International availability	Spain: tirofiban TIROFIBAN GES 50 micrograms / ml solution for perfusion EFG
	Me-too status	---
	Detail of certificates attached	Legalized Scanned Copy CoPP Certificate No: 2017/02602 Certifying Authority: Agencia Espanola Del Medicamento Y Productos Sanitarios (Spanish Medicines and Health Products Agency) Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 05-10-2017 Expiry : 1 year GMP certificate Certificate No: ES/094HVI/17 Certifying Authority: Agencia Espanola Del Medicamento Y Productos Sanitarios (Spanish Medicines and Health Products Agency) Validity: 17-01-2018 Distribution Agreement M/s Altan Pharma Limited , 2 Harbour Square, Crofton Road Dun Laoghair , Co. Dublin, Ireland M/s Medinet Pharmaceuticals ,Building No. 601, First Floor , Main Peshawar Road, Near Lane No. 5, Rawalpindi
	Stability Studies	Packaging Material: Nexcel M312 30 Months (2 Batches) Condition: 30/65%RH 24 Months (1 Batches) Condition: 30/65%RH 6 Months Condition:40/<25%RH
	Previous Remarks of the Evaluator.	• Clarify the difference between product license owner and product license holder mentioned on Form 5A. License Holder/MAH G.E.S Genericos Espanoles Laboratorio, S. A. Colquide 6-Portal 2,1 –Oficina F 28230 Las Rozas Madrid Spain Product Owner M/s Altan Pharma Limited , 2 Harbour Square, Crofton Road Dun Laoghair , Co. Dublin, Ireland Both companies belong to same shareholder Altan Pharma Limited. Tha Altan Pharma Limited is the ultimate shareholder of its affiliate G.E.S Genericos Espanoles Laboratorios and Biomendi , S. A. • "Not require any special storage condition".

		• Test for Water loss has been determined i.e. test for semi-permeable membrane. Shortcomings • Name of drug in COPP is TIROFIBAN GES 50 micrograms / ml solution for perfusion EFG. • Valid drug sale license is missing Provide notary attested photocopy. Applied for Renewal, not yet received.
	Previous Decision: Registration Board in its 285th meeting Deferred for the following reasons: • Clarification regarding the difference in brand name mentioned on COPP i.e. "TIROFIBAN GES 50 micrograms / ml solution for perfusion EFG" and on Form • 5A i.e. "Thrombostat Injection 12.5mg/250mg Solution for Infusion". • Submission of valid drug sale license. • Justification for submission of stability data at 30 °C ± 2 °C/65% RH ± 5% RH as the requirement for aqueous-based products packaged in semi-permeable containers is at 30 °C ± 2 °C/35% RH.	
	Evaluation by PEC: The firm has submitted as under: • The brand name in Spain is as mentioned on COPP that is "Tirofiban GES 50micrograms/ml solution for perfusion EFG" but we are proposing the brand name "Thrombostat Injection" for Pakistan. Both the products are same only the brand name is different in Pakistan. • We have been authorized by the principal for this brand name (copy of communication via e-mail enclosed) and we have received from the Trade marks registry, Karachi, the certificate of Registration of trade mark section 33 (4) for "Thrombostat" dated, 04 Oct. 2018 (copy enclosed). • Copy of valid DSL for M/s Medinet Pharmaceuticals, Building No. 601, Lane No. 5, Main Peshawar Road, District Rawalpindi, valid upto 13-12-2019. • Firm has submitted stability studies data for three batches at 30 °C ± 2 °C/35% ± 5% RH.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	
392.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals [Pakistan](pvt). Ltd, Country Head Office: 65- Main Boulevard, Gulberg, Lahore, Pakistan.
	Detail of Drug Sale License	Valid upto: 28-06-2020
	Name and address of manufacturer	M/s Servier (Ireland) Industries ltd., Gorey Road, Arklow Co Wicklow, Ireland.
	Name and address of marketing authorization holder	M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 12544: 05-4-2018
	Fee including differential fee	PKR 50,000/-: 05-04-2018
	Brand Name +Dosage Form + Strength	COVERSAM 5/10 tablet
	Composition	Each tablet contains: Perindopril Arginine ……5mg Amlodipine besylate eq. to Amlodipine……. 10mg
	Finished Product Specification	Innovator's Specs.
	Pharmacological Group	Anti- Hypertensive
	Shelf life	03-Years (demanded)
	Demanded Price	As per SRO
	Pack size	30's
	International availability	Perindopril/Amlodipine. 5mg/10mg. Tablets IC0041-013-002. Approved in HPRA, Ireland.
	Me-too status	NA.
	Detail of certificates attached	• Original and Legalized Certificate of Pharmaceutical Product (COPP). • Sole Agency agreement (Expired).

		• Copy of Valid Drug Sale License. • Credentials of the manufacturer. • GMP inspection report of the manufacturer conducted on 31st March 2017 wherein stated that the firm comply with the requirements of the EU Guide to GMP.
	Remarks of the Evaluator. • Copy of Sole Agency agreement submitted notarized from Lahore, wherein it is stated that, "This agreement shall thereafter remain en-forced until September 30, 2016. It shall thereafter be automatically renewed for subsequent one (1) year period." • Undertaking that the applied brand name is not similar or has no resemblance (look alike- sound alike) with already registered drugs to justify the fee submitted.	
	Previous Decision: Registration Board in its286th meeting deferred for submission of original, valid and legalized sole agency agreement.	
	Evaluation by PEC: Firm has submitted notarized copy of "Purchase and Supply Agreement" signed on 1st November 2018, between M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France and M/s Servier Research and Pharmaceuticals Pakistan (pvt). Ltd, 65- Main Boulevard, Gulberg, Lahore, Pakistan.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	
393.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals [Pakistan](pvt). Ltd, Country Head Office: 65- Main Boulevard, Gulberg, Lahore, Pakistan.
	Detail of Drug Sale License	Valid upto: 28-06-2020
	Name and address of manufacturer	M/s Servier (Ireland) Industries ltd., Gorey Road, Arklow Co Wicklow, Ireland.
	Name and address of marketing authorization holder	M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 12544: 05-4-2018
	Fee including differential fee	PKR 50,000/-: 05-04-2018
	Brand Name +Dosage Form + Strength	COVERSAM 10/10 tablet
	Composition	Each tablet contains: Perindopril Arginine ……10mg Amlodipine besylate eq. to Amlodipine……...10mg
	Finished Product Specification	Innovator's Specs.
	Pharmacological Group	Anti- Hypertensive
	Shelf life	03-Years (demanded)
	Demanded Price	As per SRO
	Pack size	30's
	International availability	Perindopril/Amlodipine. 10mg/10mg. Tablets IC0041-017-002. Approved in HPRA, Ireland.
	Me-too status	NA.
	Detail of certificates attached	• Original and Legalized Certificate of Pharmaceutical Product (COPP). • Sole Agency agreement (Expired). • Copy of Valid Drug Sale License. • Credentials of the manufacturer. • GMP inspection report of the manufacturer conducted on 31st March 2017 wherein stated that the firm comply with the requirements of the EU Guide to GMP.
	Remarks of the Evaluator. • Copy of Sole Agency agreement submitted notarized from Lahore, wherein it is stated that, "This agreement shall thereafter remain en-forced until September 30, 2016. It shall thereafter be automatically renewed for subsequent one (1) year period."	

	• Undertaking that the applied brand name is not similar or has no resemblance (look alike- sound alike) with already registered drugs to justify the fee submitted.	
	Previous Decision: Registration Board in its286th meeting deferred for submission of original, valid and legalized sole agency agreement.	
	Evaluation by PEC: Firm has submitted notarized copy of "Purchase and Supply Agreement" signed on 1st November 2018, between M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France and M/s Servier Research and Pharmaceuticals Pakistan (pvt). Ltd, 65- Main Boulevard, Gulberg, Lahore, Pakistan.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	
394.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals [Pakistan](pvt). Ltd, Country Head Office: 65- Main Boulevard, Gulberg, Lahore, Pakistan.
	Detail of Drug Sale License	Valid upto: 28-06-2020
	Name and address of manufacturer	M/s Servier (Ireland) Industries ltd., Gorey Road, Arklow Co Wicklow, Ireland.
	Name and address of marketing authorization holder	M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 12544: 05-4-2018
	Fee including differential fee	PKR 50,000/-: 05-04-2018
	Brand Name+Dosage Form+Strength	COVERSAM 5/5 tablet
	Composition	Each tablet contains: Perindopril Arginine ……5mg Amlodipine besylate eq. to Amlodipine…… .5mg
	Finished Product Specification	Innovator's Specs.
	Pharmacological Group	Anti- Hypertensive
	Shelf life	03-Years (demanded)
	Demanded Price	As per SRO
	Pack size	30's
	International availability	Perindopril/Amlodipine. 5mg/5mg. Tablets IC0041-012-002. Approved in HPRA, Ireland.
	Me-too status	NA.
	Detail of certificates attached	• Original and Legalized Certificate of Pharmaceutical Product (COPP). • Sole Agency agreement (Expired). • Copy of Valid Drug Sale License. • Credentials of the manufacturer. • GMP inspection report of the manufacturer conducted on 31st March 2017 wherein stated that the firm comply with the requirements of the EU Guide to GMP.
	Remarks of the Evaluator. • Copy of Sole Agency agreement submitted notarized from Lahore, wherein it is stated that, "This agreement shall thereafter remain en-forced until September 30, 2016. It shall thereafter be automatically renewed for subsequent one (1) year period." • Undertaking that the applied brand name is not similar or has no resemblance (look alike- sound alike) with already registered drugs to justify the fee submitted.	
	Previous Decision: Registration Board in its286th meeting deferred for submission of original, valid and legalized sole agency agreement.	
	Evaluation by PEC: Firm has submitted notarized copy of "Purchase and Supply Agreement" signed on 1st November 2018, between M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France and M/s Servier Research and Pharmaceuticals Pakistan (pvt). Ltd, 65- Main Boulevard, Gulberg, Lahore.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	

395.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals [Pakistan](pvt). Ltd, Country Head Office: 65- Main Boulevard, Gulberg, Lahore, Pakistan.
	Detail of Drug Sale License	Valid upto: 28-06-2020
	Name and address of manufacturer	M/s Servier (Ireland) Industries ltd., Gorey Road, Arklow Co Wicklow, Ireland.
	Name and address of marketing authorization holder	M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France.
	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 12544: 05-4-2018
	Fee including differential fee	PKR 50,000/-: 05-04-2018
	Brand Name +Dosage Form + Strength	COVERSAM 10/5 tablet
	Composition	Each tablet contains: Perindopril Arginine ……10mg Amlodipine besylate eq. to Amlodipine…… …5mg
	Finished Product Specification	Innovator's Specs.
	Pharmacological Group	Anti- Hypertensive
	Shelf life	03-Years (demanded)
	Demanded Price	As per SRO
	Pack size	30's
	International availability	Perindopril/Amlodipine. 10mg/5mg. Tablets IC0041-016-002. Approved in HPRA, Ireland.
	Me-too status	**NA.**
	Detail of certificates attached	• Original and Legalized Certificate of Pharmaceutical Product (COPP). • Sole Agency agreement (Expired). • Copy of Valid Drug Sale License. • Credentials of the manufacturer. • GMP inspection report of the manufacturer conducted on 31st March 2017 wherein stated that the firm comply with the requirements of the EU Guide to GMP.
	Remarks of the Evaluator. • Copy of Sole Agency agreement submitted notarized from Lahore, wherein it is stated that, "This agreement shall thereafter remain en-forced until September 30, 2016. It shall thereafter be automatically renewed for subsequent one (1) year period." • Undertaking that the applied brand name is not similar or has no resemblance (look alike- sound alike) with already registered drugs to justify the fee submitted.	
	Previous Decision: Registration Board in its286th meeting deferred for submission of original, valid and legalized sole agency agreement.	
	Evaluation by PEC: Firm has submitted notarized copy of "Purchase and Supply Agreement" signed on 1st November 2018, between M/s Les laboratories Servier, 50 rue Carnot, 92284, Suresnes Cedex, France and M/s Servier Research and Pharmaceuticals Pakistan (pvt). Ltd, 65- Main Boulevard, Gulberg, Lahore, Pakistan.	
	Decision: Approved with Innovator's specifications.as per Policy for inspection of Manufacturer abroad.	

Case No. 06 Registration Applications of Drugs for which Stability Study Sata is Submitted.

a. Deferred Cases.

396.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals Pvt. Ltd, Karachi.
	Brand Name+Dosage Form+ Strength	Iburo Injection 800mg/8ml
	Composition	Each vial contains: 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 Rs. 13,5000/10's vial
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA 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 (Container closure system)	Glass Vial		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6 Months(on going) 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 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 respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Yes Invoice No:442831 Ibuprofen 40 Microns ADC Attested Invoice dated: 09-10-2017 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. 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) Registration of Establishment No. 3011012288 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. 903 vials sent for stability, remaining vials utilized in initial test analysis 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 • Complete analysis at single frequency of stability at 3rd and 6th month consist of at least 15 runs • At 6th month time point, in analysis of Ibuprofen sequence of injections started on Saturday, July 07, 2018 at 3:38:01 PM • 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	• Method of analysis of assay has gradient program of 75 minutes • Complete analysis at single frequency of stability at 3rd and 6th month consist of at least 15 runs

	and sample. (Real time Condition).	• Similarly, at 3rd month time point, sequence of injections started on Tuesday, April 03, 2018 at 3:37:22 PM and • 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 Injectionand 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:

1. Dr. Rafeeq Alam, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board.
2. Mr. Aslam Shah, 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 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. Batch No. | Quantity Imported 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: • Postal Audit checklist • 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 ofIburo 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.

<table>
<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 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>
</table>

37	Any other query raised by the Pharmaceutical Evaluation Cell? 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".	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. 2. The panel disagrees with the firm's response and conclude the peak to be of mobile phase.

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 of 288th meeting: 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.

Remarks of Evaluator:

Firm has submitted as under:

- To investigate the issue of extra peak eluted in analysis of IBURO 800mg/8ml Injection at 56th minute, few exercises have been performed to prove that the particular unknown peak at 56 minute was not linked with any impurity, degradation or related substance
- To further support our claim that the said unknown peak is due to chromatographic condition gradient system generated, we have performed following exercises:

EXERCISE # 1:

- Analysis with extended run time of 100 minutes instead of 75 minutes inject the mobile phase, standard, sample and impurity standards to see whether any impurity eluted after the normal run time.

OBSERVATION:

- No peak of API and any impurity related to API were eluted after normal stop time i.e. 75 minutes.
- The approx. relative retention time of ibuprofen and its impurities (as listed below) and none of these impurities were observed at 56th minute.
- Kindly note a peak is eluted at 56th minute when we have a change in ratio of mobile phase in gradient programme at 55th minute.

TIME	MOBILEPHASE A	MOBILE PHASE B
25	100	0
55	15	85
70	15	85

CONCLUSION:

- None of these impurities were eluted or gave peak at 56th minute. Hence, it is due to system generated jerk because of significant change in gradient program.
- Reference chromatograms of mobile phase, standard, sample and impurity standards are attached and marked as annexure 1.

EXERCISE # 2:

- To Identify that any API impurity is eluting at 56 minutes the fraction discharge of sample and standard at run time 55 minute ± 10 minutes are collected and inject on same HPLC system

OBSERVATION:

- During whole run time, no peak of API and its related impurity is observed only the same peak was observed at same retention time which was due to significant change in gradient programme

CONCLUSION:

- It was concluded that the fraction discharge which was collected and run on HPLC shows no peak of impurity, API and related compound
- However, the same response were observed which as mentioned above was due to significant change in gradient programme
- Please again note a peak is again eluted at 56th minute when we have a change in ratio of mobile phase in gradient programme at 55th minutes
- Reference chromatograms of fractional discharge of standard and sample are attached and marked as annexure- 2

EXERCISE # 3:

- To investigate the behavior of system due to change in gradient program at particular time , we have changed the ratio of mobile phase at 60 minutes instead of 55 minutes and again injected mobile phase, standard , sample and impurity standard

OBSERVATION:

- It was observed that after changing gradient program, the peak which was observed at 56 minutes shifted to 61 minutes

CONCLUSION:

- After this study we have concluded that the said peak is purely system generated jerk because of significant change in mobile phase ratio
- Reference chromatograms are attached and marked as annexure - 3

Firm has also submitted relevant chromatograms for the above cited studies.

Decision: Registration Board decided to approve registration of "Iburo (Ibuprofen) 800mg/8ml Injection by M/s Sami Pharmaceuticals Pvt. Limited, 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.

b. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
397.	M/s Macter International Ltd, F-126, SITE, Karachi.	Sacval tablet Each film coated tablet contains: Sacubitril…….49mg Valsartan ….. 51mg (Neprilysin inhibitor, & Angiotensin receptor blocker)	Form 5D Dy. No. 3920, 24-05-2017 PKR 50,000/-: 24-05-2017 Rs. 600/tablet	**USFDA** approved Last GMP inspection report date 14-03-2017 concluding good level of GMP compliance.
	Evaluation by PEC: The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board. Details of submitted data are as under:			

STABILITY STUDY DATA	
Drug	Sacval tablet
Name of Manufacturer	M/s Macter International Ltd, F-126, SITE, Karachi.
Manufacturer of API	M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Jinwan District, Zhuhai City, Guangdong province, China.
API Lot No.	57317060103
Description of Pack	Alu-Alu blister packed in unit carton

(Container closure system)			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3 & 6 months Real Time: 0,3,6 months		
Batch No.	001P	002P	003P
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	20-01-2018	20-01-2018	20-01-2018
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.	GMP certificate (certificate# GD20160649) issued by China Food And Drug Administration, valid upto 13-11-2021, in the name of M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Jinwan District, Zhuhai City, Guangdong province, China.
3.	Protocols followed for conduction of stability study and details of tests.	No
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 dated 31-10-2017 has been submitted for import of Sacubitril & Valsartan (1:1). Quantity: 2 Kgs.
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 GMP Inspection Report Date & Remarks
398.	M/s Macter International Ltd, F-126, SITE, Karachi.	Sacval tablet Each film coated tablet contains: Sacubitril…… 24mg	Form 5D Dy. No. 3918, 24-05-2017 PKR 50,000/-: 24-	**USFDA** approved Last GMP inspection report date 14-03-2017 concluding good level of GMP

		Valsartan ….. 26mg (Neprilysin inhibitor, & Angiotensin receptor blocker)	05-2017 Rs. 600/tablet	compliance.

Evaluation by PEC:
The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board.
Details of submitted data are as under:

STABILITY STUDY DATA			
Drug	Sacval tablet		
Name of Manufacturer	M/s Macter International Ltd, F-126, SITE, Karachi.		
Manufacturer of API	M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Jinwan District, Zhuhai City, Guangdong province, China.		
API Lot No.	57317060103		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3 & 6 months Real Time: 0,3,6 months		
Batch No.	001P	002P	003P
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	20-01-2018	20-01-2018	20-01-2018
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.	GMP certificate (certificate# GD20160649) issued by China Food And Drug Administration, valid upto 13-11-2021, in the name of M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Jinwan District, Zhuhai City, Guangdong province, China.
3.	Protocols followed for conduction of stability study and details of tests.	No
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 dated 31-10-2017 has been submitted for import of Sacubitril & Valsartan (1:1). Quantity: 2 Kgs.
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 GMP Inspection Report Date & Remarks
399.	M/s Macter International Ltd, F-126, SITE, Karachi.	Sacval tablet Each film coated tablet contains: Sacubitril…….97mg Valsartan ….. 103mg (Neprilysin inhibitor, & Angiotensin receptor blocker)	Form 5D Dy. No. 3919, 24-05-2017 PKR 50,000/-: 24-05-2017	**USFDA** approved Last GMP inspection report date 14-03-2017 concluding good level of GMP compliance.
	Evaluation by PEC: The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board. Details of submitted data are as under:			

STABILITY STUDY DATA

Drug	Sacval tablet		
Name of Manufacturer	M/s Macter International Ltd, F-126, SITE, Karachi.		
Manufacturer of API	M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Jinwan District, Zhuhai City, Guangdong province, China.		
API Lot No.	57317060103		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3 & 6 months Real Time: 0,3,6 months		
Batch No.	001P	002P	003P
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	20-01-2018	20-01-2018	20-01-2018
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.	GMP certificate (certificate# GD20160649) issued by China Food And Drug Administration, valid upto 13-11-2021, in the name of M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Jinwan District, Zhuhai City, Guangdong province, China.
3.	Protocols followed for conduction of stability study and details of tests.	No
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 dated 31-10-2017 has been submitted for import of Sacubitril & Valsartan (1:1). Quantity: 2 Kgs.
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 Sacval 24mg+26mg, 49mg+51mg, 97mg+103mg (Sacubitril - Valsartan) Tablets by M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Vol. I) dated 06th March, 2019.
Investigation Date and Time: 23th April, 2019 (Afternoon).
Investigation Site: M/s. Macter International Ltd., F-216, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Macter International Ltd., F-216, S.I.T.E, Karachi for registration of Sacval (Sacubitril - Valsartan) 24mg+26mg, 49mg+51mg, 97mg+103mg Tablets. PER Division considered scientifically rational laboratory scale data submitted by the firm as pre-requisite of registration being new formulation 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 and Dean, Faculty of Pharmacy, Ziauddin University. (Member Registration Board)
2. Dr. Saif-ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi.
3. Dr. Krishan Das, Assistant Director, 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:

Detail of Investigation:

S. No.	Question	Observation

1.	Do you have documents confirming the import of Sacubitril - Valsartan API including approval from DRAP?	The firm has imported 2Kg Sacubitril - Valsartan (Co-crystal) API from M/s. Zhuhai Rundu Pharmaceutical Co. Ltd vide invoice No. RIS17087 dated: 10.10.2017. There is proper approval from DRAP Karachi on Form 6 (2966-17)
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular manufacturer of API is the vendor evaluation process based on audit and other criteria like manufacturer GMP status, DMF source etc.
3.	Do you have documents confirming the import of Sacubitril - Valsartan reference standard and impurity standards?	The firm has imported Sacubitril - Valsartan working standard and two impurity standards from the API manufacturer.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has Certificate of Analysis of API, working standard of API and impurities standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificates for API manufacturer issued by Zhuhai Food & Drug administration, China.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method of testing.
7.	Do you have stability studies reports on APIs?	The firm has stability studies report on API (Sacubitril - Valsartan) 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 as per SIM method. The process related impurities have been quantified, however, no degradation product has been observed.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of API (Sacubitril - Valsartan) working standard and impurity standard.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Microcrystalline cellulose, Hydroxypropyl cellulose, Crospovidone, Magnesium stearate, Talcum Powder & Colloidal Silicon dioxide.
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 for the excipients used.
14.	Do you have written and authorized protocols for the development of Sacubitril - Valsartan Tablets?	The firm has written and authorized protocol for the development of Sacval (Sacubitril - Valsartan)24mg+26mg, 49mg+51mg, 97mg+103mg tablets.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug Excipient compatibility studies as composition of their product is similar to that of innovator product (Entresto Tablets, from Novartis, UK.
16.	Have you performed comparative dissolution studies?	The firm has perform comparative dissolution profile with innovator product. The firm's product shows comparable dissolution profile.
17.	Do you have product development (R&D) section	The firm has product development (R&D) section with requisite facilities.

<table>
<tr><td>18.</td><td>Do you have necessary equipments available in product development section for development Sacubitril - Valsartan Tablets?</td><td>The firm has all the necessary equipment available in product development section for the development of Sacubitril - Valsartan tablets.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The 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 proper maintenance / calibration / re-qualification program for the equipment used in 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 in PD section with proper knowledge and training in Product Development including 01 Ph.D., 04 Pharmacists 04 MSc Chemistry and 01 BEMS & M.Phil.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Sacubitril - Valsartan Tablets required?</td><td>The firm has manufactured three stability batches as follows;
Sacubitril - Valsartan 24mg +26mgtablets:
<table>
<tr><th>Sr. No.</th><th>B. No.</th><th>Batch size</th></tr>
<tr><td>1</td><td>001P</td><td>1500</td></tr>
<tr><td>2</td><td>002P</td><td>1500</td></tr>
<tr><td>3</td><td>003P</td><td>1500</td></tr>
</table>
Sacubitril - Valsartan 49mg+51mg tablets:
<table>
<tr><th>Sr. No.</th><th>B. No.</th><th>Batch size</th></tr>
<tr><td>1</td><td>001P</td><td>1500</td></tr>
<tr><td>2</td><td>002P</td><td>1500</td></tr>
<tr><td>3</td><td>003P</td><td>1500</td></tr>
</table>
Sacubitril - Valsartan 97mg+103mg tablets:
<table>
<tr><th>Sr. No.</th><th>B. No.</th><th>Batch size</th></tr>
<tr><td>1</td><td>001P</td><td>1500</td></tr>
<tr><td>2</td><td>002P</td><td>1500</td></tr>
<tr><td>3</td><td>003P</td><td>1500</td></tr>
</table>
The tablets are packed in Alu Alu blisters with pack size 14s for both potencies.</td></tr>
<tr><td>23.</td><td>Do you have any 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 tablets required per testing frequency and number of 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 records of production of stability batches.</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 the stability testing of Sacubitril - Valsartan tablets.</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 for testing of stability batches of finished product i.e. Sacubitril - Valsartan tablets based on the API method of testing provided by the API manufacturer.</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 given by any other lab?</td><td>The firm has developed and validated method based on API manufacturer for testing of finished product.</td></tr>
</table>

28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Sacubitril - Valsartan and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the API (Sacubitril - Valsartan) and the finished drug Sacval (Sacubitril - Valsartan) tablets.
29.	Do your method of analysis stability indicating?	The firm method of analysis is stability indicating as evidence by forced degradation studies and spiking studies of the two major impurities. Both the impurities are process related and the forced degradation studies also confirmed that there is no degradation product.
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 Sacubitril - Valsartan testing?	Audit Trail on the testing reports on Sacubitril - Valsartan API and Sacval tablets is available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has only remaining quantities of stability batches kept on real-time stability testing.
33.	Do you have stability batches kept on stability testing?	The firm has three lab scale batches kept on stability studies for real time stability testing. Currently 12 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in Sacubitril - Valsartan Tablets production and analysis?	The firm has valid calibration status for the equipment used in Sacval (Sacubitril - Valsartan) tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has adequate monitoring and control system 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 are GMP compliant at time of inspection.

Conclusions:

1. On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Sacval 24mg+26mg (Sacubitril - Valsartan) Tablets , Sacval 49mg+51mg (Sacubitril - Valsartan) Tablets, Sacval 97mg+103mg Tablets (Sacubitril - Valsartan) Tablets is verifiable satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are GMP compliant and well suited for the manufacturing of Sacval 24mg+26mg (Sacubitril - Valsartan) Tablets, Sacval 49mg+51mg (Sacubitril - Valsartan) Tablets , Sacval 97mg+103mg (Sacubitril - Valsartan) Tablets.

Recommendation

1. Keeping in view above mentioned conclusion registration of Sacval 24mg+26mg, 49mg+51mg, 97mg+103mg tablets is recommended in the name of manufacturer.

Decision: Registration Board decided to approve registration of "Sacval tablet 24/26 (Sacubitril/valsartan)", "Sacval tablet 49/51 (Sacubitril/valsartan)" "Sacval tablet 97/103 (Sacubitril/valsartan)" by M/s Macter International Ltd, F-126, SITE, Karachi.Manufacturer will place first three production batches of all 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	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks

		Group, Finished Product Specification		
400.	M/s Indus Pharma (Pvt.) Limited, Plots No. 26, 27, 63-67, Sector-27, Korangi Industrial Area, Karachi.	Canazin tablet 300mg Each film-coated tablet contains: Canagliflozin (as Canagliflozin Hemihydrate.300mg (Anti-Diabetic) Manufacturers	Form-5-D Diary. No: 17883 Dated: 15-05-2018 Rs.50,000/- (15-05-2018) 10's ; as per DPC	Invokana 300mg film-coated tablets of M/s Napp Pharmaceuticals, Limited (MHRA Approved) Not applicable GMP inspection report conducted on 14-11-2017, concluding an acceptable level of GMP compliance.
	Evaluation by PEC: - Firm has provided 06 months accelerated and 06 months real time stability data for 03 batches.			

STABILITY STUDY DATA			
Drug	Canazin tablet 300mg (Canagliflozin)		
Name of Manufacturer	M/s Indus Pharma (Pvt.) Limited, Plots No. 26, 27, 63-67, Sector-27, Korangi Industrial Area, Karachi.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatec Co. Limited, China.		
API Lot No.	RD-CLF (hemihydrate)- 201705101		
Description of Pack (Container closure system)	Alu- Alu Blister strip of 2x5 tablets		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5% RH Real time : 30°C ± 2°C / 65% ± 5% RH		
Time Period	Accelerated: 06 months Real time: 06 months		
Frequency	Accelerated: 0,3,6 months Real time: 0,3,6 months		
Batch No.	TR-01-Can 300 Tab	P-1/ Can 300mg Tablet	P-2/ Can 300mg Tab
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	08-2017	09-2017	09-2017
Date of Initiation	11-09-2017	20-09-2017	20-09-2017
No. of Batches	03		
Date of Submission	15-05-2018 (Diary No. 17883)		

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.	M/s Nantong Chanyoo Pharmatech Co. Limited, China: • Photocopy of GMP Certificate issued by People's Republic of China, Nantong, Jiangsu is submitted. • Photocopy of Certificate of GMP compliance of a manufacturer by Agency for medicinal products and medical devices of the Republic

		of Solvenia 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.	Photocopy of ADC (Karachi) attested Commercial Invoice is submitted. Commercial invoice is from M/s Changzhou Pharmaceutical Factory, No. 518 Loading East Road, Changzhou, 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

REMARKS OF EVALUATOR

Sr.#	Deficiency/ Observation	Response by M/s Indus Pharma
i.	Initial analysis of finished dosage form is not submitted.	Raw data sheets of initial analysis showing relevant calculations still need to be submitted.
ii.	Justify the time gap between withdrawal of sample and its analysis.	The main reason for time gap between withdrawal and analysis of stability samples of Canazin tablets is to reduce workload of analysis to club all three batches (i.e. B. No. Tr-1-Can 300 tab, P-1-Can 300 tab and P-2 Can 300 tab) including accelerated and long term-analysis. Canazin tablets B No. Tr-1-Can 300 tab was withdrawn at 12-03-2018 while P-1 Can 300 tab and P-2-Can 300 tab at 20-03-2018 from stability chamber for 6 month analysis. Analysis was started at 20-03-2018 and was done at 02-04-2018.
iii.	Provide system generated (U-V 1800) Absorbance Values of all time points.	Reply needs to be submitted.

FOR PANEL:

- Verify Dissolution Testing of all Time Points on U-V 1800.
- The Assay Results in Stability Data Sheets of Initial Testing do not match with the Summary Report of the First Batch i.e. Batch No. Tr-1-Can 300 Tab.
- In the submitted reply, for the first batch i.e. Batch No. TR-01-Can 300mg Tab, Dissolution is 92.96% while in the stability sheet, it is mentioned as 93.19%.
- The percentage of assay in the submitted reply of initial analysis is 100.43% while in the stability sheet, it is mentioned as 100.06%.
- Raw data sheets of initial analysis showing relevant calculations still need to be submitted.
- Regarding justification of the time gap between withdrawal of sample and its analysis, firm had replied that analysis was started at 20-03-2018 and was done at 02-04-2018.While in the submitted raw data sheets of Canazin tablets Batch No. Tr-1-Can 300 Tab ; withdrawal Date is mentioned as 11-03-18 and Analysis Date is mentioned as 02-04-2018. Justification / Clarification is needed.

401.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26, 27, 63, 64, 65, 66 & 67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Canazin Film Coated Tablets 100mg
	Diary No. Date of R& I & fee	Dy No. 11346, Rs: 50,000/- 28-03-2018

	Composition	Each film coated tablet contains:- Canagliflozin as hemihydrate ….100mg
	Pharmacological Group	Sodium-glucose co-transporter 2 (SGLT2) inhibitors ATC Code: A10BK02 Anti-diabetic
	Type of Form	Form 5-D
	Finished Product Specification	Manufacturer Specs.
	Pack size & Demanded Price	Pack of 10's
	Approval status of product in Reference Regulatory Authorities.	Invokana tablet-USFDA approved
	Me-too status	Not applicable
	GMP status	Last inspection report 16-8-2017 firm was considered to be operating at an acceptable level of compliance with GMP.
	Remarks of the Evaluator.	• Method is as per USFDA.

STABILITY STUDY DATA

Drug	Canazin Film Coated Tablets 100mg		
Name of Manufacturer	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26, 27, 63, 64, 65, 66 & 67, Sector 27 Korangi Industrial Area, Karachi		
Manufacturer of API	M/s NANTONG Chanyoo Pharmatech Co., Ltd, China		
API Lot No.	RD-CLF(hemihydrate)-201705101		
Description of Pack (Container closure system)	Alu-Alu blister strip packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Real time: 0,3,6 (months) Accelerated: 0,3,6 (months)		
Batch No.	TR-01-Can 100 tab	P-1 Can 100 tab	P-2 Can 100 tab
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	08-2017	08-2017	08-2017
Date of Initiation	08-2019	08-2019	08-2019
No. of Batches	03		
Date of Submission	28-03-2018 (Dy No. 11346)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes RD-CLF (hemihydrate)-201705101
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.	Yes
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

. The firm has claimed In House specifications and the product is not present in USP/BP.
i. Approved in USFDA with box warning.

Shortcoming	**Reply**
Commercial invoice issuer Changzhou Pharmaceutical Factory (3.2kg) is mentioned. Whereas GMP is of M/s NANTONG Chanyoo Pharmatech Co., Ltd, China.	Firm submitted relationship letter.
The stability data of initial time point shows following discrepancies: • Batch no. TR-01—Can 100 mg, the COA mentions assay 107.00% however, in stability data sheet is 107.03%. • Batch no. TR-01—Can 100 mg, the COA mentions Dissolution results as 101.70% however, in stability data sheet is 102.77%. • Batch no. P-1—Can 100 mg, the COA mentions Dissolution results as 99.72% however, in stability data sheet is 100.76%. • Batch no. P-2—Can 100 mg, the COA mentions Dissolution results as 93.46% however, in stability data sheet is 94.44%. Clarify and justify the same.	Firm has submitted that the identified difference is due to typographical error and has revised all stability data sheets.

Remarks of the Evaluators:
The following observations were noted in the stability files as mentioned against each.

Sr. No.	**Name of Applicant**	**Brand Name, Composition**	**Observations**
1.	M/s Indus Pharma (Pvt.) Limited, Plots No. 26, 27, 63-67, Sector-27, Korangi Industrial Area, Karachi.	Canazin tablet 300mg Each film-coated tablet contains: Canagliflozin (as Canagliflozin Hemihydrate)…….300mg	• Confirmation of performance of Dissolution Testing on UV 1800 as UV spectra and system generated results have not been provided by the firm. • Confirmation of performance of assay and dissolution at initial time point as the assay results mentioned in Stability Data Sheets of Initial Testing do not match with the COA of Batch No. Tr-1-Can 300 Tab.
			Batch No TR-01-Can 300mg / Stability Summary report / COA Assay / 100.06% / 100.43% Dissolution / 93.19% / 92.96%
			• Confirmation and justification regarding the time gap of 22 days between withdrawal of sample from stability chamber and its analysis for Batch No. Tr-1-Can 300 Tab. Sample withdrawal Date :11-03-18 Analysis Date: 02-04-2018.
2.	M/s Indus Pharma (Pvt.) Limited, Plots No. 26, 27, 63-67, Sector-27, Korangi Industrial Area, Karachi.	Canazin tablet 100mg Each film-coated tablet contains: Canagliflozin (as Canagliflozin Hemihydrate)…….100mg	Confirmation of performance of assay and dissolution at initial time point as the assay result mentioned in Stability Data Sheets of Initial Testing do not match with the COA. Tests / Stability Summary report / COA

			TR-01—Can 100 mg
			Assay: 107.03%. / 107.00%
			Dissolution: 102.77%. / 101.70%
			P-1—Can 100 mg
			Dissolution: 100.76%. / 99.72%
			P-2—Can 100 mg
			Dissolution: 94.44%. / 93.46%
			Firm has submitted that the identified difference is due to typographical error and has revised all stability data sheets which needs to be confirmed.

Now, the firm has also claimed exemption. However, as per last product specific inspection report of Sacutan 97mg/103mg "The HPLC Software is 21 CFR complaint as per record available with the firm. However, practically implementation of 21 CFR part-11 compliance needs further improvement.by the firm."

Therefore on the directions of Chairman Registration Board letter was issued to M/s Indus Pharma, Karachi regarding improvements made so far by the firm for practical improvement of 21 CFR II compliance of HPLC software as pointed out in last PSI inspection report. The firm has replied that the following points already exist.

1. The HPLC software is 21 CFR part 11 complaint where all user level are properly defined.
2. No user or main user can delete, edit or manipulate data from software.
3. All actions are recorded in audit trails.
4. Created strict policies on windows and disable options like "Delete, Copy, Paste and rename" of any file from user level.

Furthermore, the following improvement are being made in order to strengthen it further.

1. A new HPLC of "Agilent Infinity series" has been installed in Quality Control Laboratory & two more are under procurement and will be commissioned by the mid of 2019.
2. Chromatography Data System (CDS) Software is also being procured for compliance and Data Security.

With the ever-evolving emphasis on data security, data integrity, and compliance, it is of vital importance that the software provides comprehensive preventive and detection technical controls. This will enable to meet the latest regulatory requirements and ensure the highest levels of data quality.

Decision of 287th meeting: Registration Board decided to constitute panel for the Canazin 100mg & Canazin 300mg Tablet 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.

<table>
<tr><th>Brand Name, Composition</th><th>Observations</th></tr>
<tr><td>Canazin tablet 300mg
Each film-coated tablet contains:
Canagliflozin (as Canagliflozin Hemihydrate) …….. 300mg</td><td>

Confirmation of performance of Dissolution Testing on UV 1800 as UV spectra and system generated results have not been provided by the firm.
Confirmation of performance of assay and dissolution at initial time point as the assay results mentioned in Stability Data Sheets of Initial Testing do not match with the COA of Batch No. Tr-1-Can 300 Tab.

<table>
<tr><td>Batch No
TR-01-Can 300mg</td><td>Stability Summary report</td><td>COA</td></tr>
<tr><td>Assay</td><td>100.06%</td><td>100.43%</td></tr>
<tr><td>Dissolution</td><td>93.19%</td><td>92.96%</td></tr>
</table>

Confirmation and justification regarding the time gap of 22 days between withdrawal of sample from stability chamber and its analysis for Batch No. Tr-1-Can 300 Tab.

Sample withdrawal Date :11-03-18
Analysis Date: 02-04-2018.
</td></tr>
<tr><td>Canazin tablet 100mg
Each film-coated tablet contains:
Canagliflozin (as Canagliflozin Hemihydrate) …….. 100mg</td><td>
Confirmation of performance of assay and dissolution at initial time point as the assay results mentioned in Stability Data Sheets of Initial Testing do not match with the COA.
<table>
<tr><td>Tests</td><td>Stability Summary report</td><td>COA</td></tr>
<tr><td colspan="3">TR-01—Can 100 mg</td></tr>
<tr><td>Assay</td><td>107.03%.</td><td>107.00%</td></tr>
<tr><td>Dissolution</td><td>102.77%.</td><td>101.70%</td></tr>
<tr><td colspan="3">P-1—Can 100 mg</td></tr>
<tr><td>Dissolution</td><td>100.76%.</td><td>99.72%</td></tr>
<tr><td colspan="3">P-2—Can 100 mg</td></tr>
<tr><td>Dissolution</td><td>94.44%.</td><td>93.46%</td></tr>
</table>
Firm has submitted that the identified difference is due to typographical error and has revised all stability data sheets which needs to be confirmed.
</td></tr>
</table>

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Canazin 100mg & 300mg Tablets (Canagliflozin) Tablets by M/s. Indus Pharma (Pvt.) Limited, Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (Vol-I) dated 20th, February, 2019.
Investigation Date and Time: 14th March, 2019 (Morning).
Investigation Site: Factory premises of M/s. Indus Pharma (Pvt.) Limited, Korangi Industrial Area, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Indus Pharma, Plots No. 26, 27, 63-67, Sector 27, Korangi Industrial Area, Karachi for registration of Canazin 100mg & 300mg (Canagliflozin) 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.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board, Islamabad.
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Dr. Sajjad Abbasi, Area FID, DRAP Office, 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:

CANAZIN 100MG & 300MG TABLETS

Sr. No	Question	Observation by Panel
1.	Do you have documents confirming the import of Canagliflozin API including approval from DRAP?	Thefirmhasimported 3.2kgCanagliflozin Hemihydrate fromM/s Nantong Chanyoo, China vide invoice no:CY117185 dated:17/05/2017 with properapprovalfromDRAP Office,Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implementedincludingPostalAudit checklist,Testing of API, DMF and GMP approval by competent authority.
3.	Do you have documents confirming the import of Canaglifloz in reference standard and impurity standard?	The firm has documents confirming the import of Canagliflozin Hemihydrate working standard and 05 major impurities standards.
4.	Do you have certificate of Analysis of the API, reference standard of the API and impurity standard?	The firm has certificate of analysis of the API,referencestandardoftheAPIand impuritystandards.
5.	Do youhave GMP certificate of API manufacturers issued by regulatory authorities of country of origin?	The firm has valid GMP certificate of the API manufacturer issued by the concerned provincial RegulatoryAuthorityofthecountryoforigin.
6.	Do you use API manufacturer method of testing fortesting API?	ThefirmhasusedAPImanufacturermethodfor testing API.
7.	Do you have stability studies report on API?	The firmhasstabilitystudies reports on the 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 performedas perSIM method.
9.	Do you have method for quantifying the impurities in the API?	The firmhasHPLCmethodforquantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remainingquantitiesof the API, its reference standard and impuritiesstandards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including lactose anhydrous, microcrystalline cellulose, hydroxy propyl cellulose, croscarmellose sodium, purified talc, magnesium stearate & opadry II 85G68918 white (same composition as that of innovator INVOKANA tablet range).
12.	Do you have documents confirming the import of the used excipients?	Thefirmhasnecessarydocumentsconfirmingtheimpor t of the used excipient.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipient used.
14.	Do you havewritten and authorized protocols for the development of Canagliflozin tablets?	The firmhas written and authorized protocols for the developmentofCanagliflozin tablets 100mg & 300mg.
15.	Have you performed Drug-excipient compatibility studies?	
16.	Have you performed comparative dissolution studies?	Thefirmhasperformedcomparativedissolutionstudies on their tablets0 (100mg & 300mg)against

		theinnovator product Invokana 100mg tablet batch no:HBL4Y00 & Invokana 300mg Tablet Batch No:GKL 9Q000.Thefirm's tablets (100mg & 300mg) have comparabledissolutionprofileswiththatoftheinnovator tablets.
17.	Doyouhaveproductdevelopment(R&D) section?	The firm does not have dedicated product development section. They have equipments for manufacturing lab scale batches. Some of these equipments are used while shifting them to the commercial manufacturing area; whereas, some equipments of commercial scale manufacturing are being used for product development. Dedicated area for product devlopement is in process. Design for the same has been finalized. New equipment is under custom clearance and will be commissioned after renovation.
18.	Do you have necessary equipment available inproduct development section for development of Canagliflozin capsules?	As above.
19.	Are the equipment in product development section qualified?	Theavailableequipmentsforproductdevelopmentsection are qualified.
20.	Do you have proper maintenance calibration/ re-qualification program for the equipment used in PD section?	Thefirmhaspropermaintenance/calibrationwithre-qualificationprogramfortheequipmentusedforproduct development.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Thefirmhasateamof05technicalpersons (04 Pharmacist & 01 M.Sc. Chemistry) for product development. These personnel have proper knowledge and training in productdevelopment.
22.	Have you manufactured three stability batches for the stability studies of Canagliflozin tablets asrequired?	The firm has manufactured three stability batches of Canagliflozin Tablets. Canagliflozin 100mg tablets having batch No. TR-01-CAN 100 TAB, P-1 /CAN 100mg TAB, P-2/CAN 100mg TAB each of 2500tablets. The tablets are packed in Alu Alu blister pack of 1x.10s Canagliflozin Tablet 300mg havingbatch#TR-01 CAN 300, P-1CAN 300mg, P-2 CAN 300mgeachof2500 tablet.The tablets are packed in Alu Alu blisters of pack size 5x2s. Firm has changed the manufacturing process from wet granulation (innovator) to direct compression.
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the quantity of tablets required pertesting frequency and the number of testingfrequencies.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. All the Log Books are properly maintained.
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 method is based upon the API method of API manufacturer which has been validated and used for the testing finish product in stability testing. The method is supported by forced degradation studies on the product hence stability indicating.
27.	Do you have method transfer studies in case	The firmhasperformed complete validation studies.

	when the method of testing being used by your firm is given by any other lab?	
28.	Do you have documents confirming the qualification of equipment/instruments being used in the test and analysis of Canagliflozin API and the finished drug?	The firm has proper documents confirming the qualification of equipment/instruments being used in the test and analysis of the API and the finished drug.
29.	Do yourmethod of analysis stability indicating?	The firm has performed forced degradation (FD) study on their product Canagliflozin Tablet 100mg& Canagliflozin Tablet 300mg for the conformance of stability indicating nature of their method for testing the finished product during stability studies.
30.	Do your HPLC software 21CFR Compliant?	1. Yes HPLC software is 21 CFR Part 11 compliant where all user levels are properly defined. 2. No user or main user can delete, edit or manipulate data from software. 3. All actions are recorded in audit trails. 4. Created strict policies on windows and disable options like "Delete, Copy, Paste and rename" of any file from user level. Furthermore, the following improvements are being made in order to strengthen it further. 1. A new HPLC of "Agilent Infinity series" has been installed in Quality Control Laboratory & two more are under procurement and will be commissioned by the mid of 2019. 2. Chromatography Data System (CDS) Software is also being procured for Compliance and Data Security. With the ever-evolving emphasis on data security, data integrity, and compliance, it is of vital importance that the software provides comprehensive preventive and detection technical controls. This will enable us to meet the latest regulatory requirements and ensure the highest levels of data quality.
31.	Can you show Audit trail reports on Canagliflozintesting?	Audittrailonthetestingreports is available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches only.
33.	Do youhave stability batches kept on stabilitytesting?	The firm has three stability batches kept on realtime stability testing. 12months studies have been completed on the sebatches with satisfactory results.
34.	Do you have valid calibration status for the equipment's used in Canagliflozin capsules production andanalysis?	The firm has valid calibration status for the equipment used in Canagliflozin 300mg tablet 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 including data loggers and centralized controlling software.
36.	Do related manufacturing area, equipment, personnel and utilitiesberated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance.
37.	**Observations of PEC?** Assay and observation results initially provided to PEC were wrong.	1. The resubmitted data is correct and has been verified from system and concerned log books.

	Correct data was resubmitted to the PEC. All revised stability data sheets needs to be confirmed.	

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Canazin 100mg & 300mg (Canagliflozin) Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Canazin 100mg & 300mg (Canagliflozin) Tablets.

Recommendations:

1. Since canagliflozin is falls in BCS Class IV (poor solubility and poor permeability) and the manufacturer has also changed the manufacturing process therefore, post registration bioequivalence studies should be conducted before marketing the product.

2. Registration of Canazin 100mg & 300mg tablets may kindly be granted in the name of the manufacturer.

Note: The firm has submitted written undertaking for post registration bioequivalence studies on the tablets (copy enclosed).

Decision: Registration Board decided to approve registration of "Canzin 100mg tablets (Canagliflozin 100 mg) and Canzin 300mg tablets (Canagliflozin 300mg) by M/s Indus Pharma (Pvt.) Ltd.Plot No. 26, 27, 63, 64, 65, 66 & 67, Sector 27Korangi 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 GMP Inspection Report Date & Remarks
402.	M/s Abbott Labs, Pak Ltd, Landhi, Karachi.	Brufen Duo tablet Each film coated tablet contains:- Paracetamol …500mg Ibuprofen …… 150mg (Analgesic, Antipyretic)	Form 5-D Diary No. 5307 dated 14-02-2018 Rs. 50,000/- dated 13-02-2018 2 x 14's, 2 x 7's	Combogesic 500/150 tablets approved by MHRA of UK

Evaluation by PEC:

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:

Details of submitted data are as under: (Dy.# 42171 dated 10-12-2018)

STABILITY STUDY DATA

Drug	Brufen Duo tablet
Name of Manufacturer	M/s Abbott Labs, Pak Ltd, Landhi, Karachi.
Manufacturer of API	Ibuprofen: M/s Shandong Xinhua Pharmaceutical Co., Ltd., China Paracetamol: M/s Zenith Chemical Industries (Pvt.) Ltd. Lahore
API Lot No.	Ibuprofen: 17112353 Paracetamol: ZPAR17-355
Description of Pack (Container closure system)	PVC-Alu foil
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 month Real Time: 0,3,6 month		
Batch No.	87654XZ	86652XZ	87653xz
Batch Size	20 Kg	20 Kg	20 Kg
Manufacturing Date	21-03-2018	27-02-2018	21-03-2018
Date of Initiation	18-04-2018	27-03-2018	18-04-2018
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.	Ibuprofen: Copy of GMP certificate (Certificate# SD20140251) issued by China Food and Drug Administration valid till 12-12-2018. Paracetamol: Copy of DML issued by DRAP, with issuance date of 15-06-2011
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.	Ibuprofen: Copy of invoice attested by ADC DRAP, Karachi dated 30-11-2017invoice has been submitted. Paracetamol: Not applicable
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 Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) Tablets by M/s. Abbott Laboratories, Pakistan Limited, Landhi, Karachi.

Reference No: F.13-11/2017-PEC(Pt) dated 18th January, 2019.
Investigation Date and Time: 28th February, 2019 (Evening).
Investigation Site: Factory premises of M/s. Abbott Laboratories, Pakistan Limited, Landhi, Karachi.
Background:

Chairman Registration Board considered the applications of M/s Abbott Laboratories, Pakistan Limited, Landhi, Karachi for registration of Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) 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.

Composition of Panel:

1. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
2. Dr. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board, Islamabad.

3. Dr. Kirshan Das, Assistant Director, DRAP Office, 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:

BRUFEN DUO 500MG / 150MG TABLETS

Sr. No.	Question	Observation by panel
1	Do you have documents confirming the import of APIs?	The firm has imported 50kg Ibuprofen (Lot # 17112353) from M/s. Shandong Xinhua Pharmaceutical Co., Ltd., China. 1500kg Paracetamol (Lot # ZPAR17-355) has been purchased locally for these batches from M/s. Zenith Chemical Industries (Pvt) Ltd., Lahore, Pakistan.
2	What was the rationale behind selecting the particular manufacturers of APIs?	There is proper vendor qualification program being implemented by the firm which includes GMP Status, provision of DMF, reference standard, impurity standards etc. However, in the instant case both the sources of both the material have already been approved by the firm for manufacturing of other registered products like Brufen Tablets and Cofcol Tablets.
3	Do you have documents confirming the import of the APIs, reference standard of the APIs and impurity standards of the APIs?	The firm has documents confirming the import of Ibuprofen. Paracetamol has been purchased locally for which there are proper documents of purchase. The firm has also imported USP reference standards of the APIs. An impurity standard for Paracetamol and two major impurity standards for Ibuprofen have also been imported from USP for which proper import documents are available.
4	Do you have certificate of Analysis of the APIs, reference standards and impurity standards?	The firm has certificates of analysis for both APIs, reference standards of the APIs and their impurities standards.
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 certificates of manufacturers of both APIs.
6	Do you use API manufacturer method of testing?	The firm has used USP methods for testing of the APIs.
7	Do you have stability studies reports on APIs?	The firm has stability studies reports on both APIs conducted by the API manufacturers.
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 methods 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 APIs.
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of the APIs, reference standards of the APIs and impurities standards.
11	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients. The excipients include: Microcrystalline cellulose, Pregelatinized Starch, Corn starch, Cross Carmellose

		sodium, talc, magnesium stearate, methocel 15cps, PEG 8000 and titanium dioxide.
12	Do you have documents confirming the import of the used excipients?	Except corn starch which is locally purchased all the other excipients are imported with proper import documents.
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 Brufen Duo tablets?	The firm has written and authorized protocols for the development of Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) Tablets.
15	Have you performed Drug-excipient compatibility studies?	Drug-excipients compatibility studies were not performed as formulation of Brufen Duo tablets is the same as that of the innovator product (Combogesic 500mg / 150mg tablets, manufactured by M/S. ICN Polfa, Poland). The firm is advised to conduct proper compatibility testing in future cases as impurities and differences of sources may impact the studies.
16	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies against the innovator product (Combogesic 500mg / 150mg tablets) while employing FDA guidance document for comparative dissolution profile. The firm formulation have comparable dissolution profile with that of the innovator product.
17	Do you have product development (R&D) section?	The firm has well equipped product development laboratory with equipment for manufacturing of tablet dosage form whereas the analytical activities are performed in routine QC lab.
18	Do you have necessary equipment available in product development section for development of tablets?	The firm has necessary equipment for product development in product development laboratory. The analytical work has been performed in routine QC lab with dedicated equipments and personnel.
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 02 qualified staff (pharmacists) in manufacturing part whereas 04 personnels (03 chemists and 01 pharmacists) in analytical part of the product development.
22	Have you manufactured three stability batches for the stability studies of Brufen Duo tablets as required?	The firm has manufactured three stability batches (pilot scale, 20kg each) for the accelerated and real time stability studies of Brufen Duo 500mg / 150mg tablets with batch No. 87654XZ, 86652XZ and 87653XZ each of 24390 tablets. The tablets are packed in PVC / Alu blisters with pack size of 2x14's and 2x7's.
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 ICH guidelines.
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 have been available with the firm.
25	Do you have protocols for stability testing of stability batches?	The firm has 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 the method for testing stability batches. The method is based upon force degradation studies.

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 the finish product has been developed and validated by M/S. I&D, Abbott Laboratory, India. The method was transferred to M/S. Abbott Laboratories, Pakistan through testing on one pilot scale batch manufactured by M/S. I&D, Abbott Lab, India as test method transfer studies as per USP requirement of method transfer.
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 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 analysis is stability indicating. The stability studies on the three stability batches show quantification of the degradation products along with the active components of the tablets.
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 and finish product testing ?	The firm showed the audit trail reports on API and finish product testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches and degradation products.
33	Do you have stability batches kept on real time stability testing?	The firm has completed accelerated stability testing. The real time stability testing is in progress on all the three stability batches. 09 months real time stability studies have been performed on all three batches with satisfactory results.
34	Do you have valid calibration status for the equipment used in the production and analysis of API and tablets?	The firm has valid calibration status for the equipment used in Brufen Duo 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 are 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 Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) 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 Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) Tablets**.**

Recommendations:

1. The firm may kindly be granted necessary registration of Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) Tablets

Decision: Registration Board decided to approve registration of "Brufen Duo 500mg / 150mg (Paracetamol / Ibuprofen) Tablets by M/s. Abbott Laboratories, Pakistan Limited, Landhi, 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.

c. Exemption from onsite verification of stability data

Cases of Exemption form onsite Investigation form submitted stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
403.	M/s Genix Pharma Pvt. Ltd. Karachi.	Empag-M Tablet 12.5mg/500mg Tablet Each film coated tablet contains: Empagliflozin .....12.5mg Metformin hydrochloride..500mg (Anti Diabetic)	Form-5-D Dy. No: 30795 Dated.12-09-2018 Rs.50,000/-(12-09-2018) 2x7's; As per SRO.	USFDA Approved. Last GMP inspection conducted on 08-08-2017, and the report concludes that firm is operating at satisfactory level of compliance of GMP.
	Evaluation by PEC: Firm has claimed innovator's Specification.			

STABILITY STUDY DATA			
Drug	Each film coated tablet contains: Empagliflozin ……12.5mg Metformin hydrochloride ……..500mg		
Name of Manufacturer	M/s Genix Pharma Pvt. Ltd. Karachi.		
Manufacturer of API	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China		
	Metformin hydrochloride: M/s Wanbury Ltd., India		
API Lot No.	**Empagliflozin:** EGLZ-RD20171101A		
	Metformin hydrochloride: MT00600118, MT00610118, MT00620118 MT00630118		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	18SB-100-01	18SB-101-02	18SB-102-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	11-04-2018	11-04-2018	11-04-2018
No. of Batches	3		
Date of Submission	43218, 19-12-2018		

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.	Empagliflozin Firm has provided copy of valid GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd, China for Empagliflozin valid till 21-01-2019, issued by Shaoguan FDA.
		Metformin HCl Firm also provided copy of GMP certificate of M/s Wanbury Ltd., India for Metformin HCl valid till

		28-07-2018 issued by Director, Drugs Control Administration, Government of Andhra Pradesh - India. Submit valid GMP certificate.
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

REQUEST OF EXEMPTION ROM 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 onsite inspection report of their product "Wymly Tablets 25 mg", which was conducted on 9th April, 2018. (Afternoon) and was presented in 281st meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software 21CFR compliance.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**EMPAGLIFLOZIN** ➢ **Declaration by WIS Pharmtec Co. Ltd, China** The firm has imported Empagliflozin API 750 g from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information. Batch No.: EGLZ-RD20171101A Mfg Date: 01-11-2017 ➢ **Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China** Invoice No. WIS170152 Quantity imported: 0.75 Kg Date of import: 29-06-2016 ADC Attestation Date: 07-12-2017 Manufacturer: Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China. Commercial invoice doesnot mention the batch no.

<table>
<tr><td></td><td></td><td>
<u>METFORMIN HCL</u>
➢ <u>Details of ADC Attested invoice commercial Invoice by WanburyLtd., India</u>
Firm has imported Metformin HCl from M/s Wanbury Ltd., India and has approval from DRAP for import.
Date of Import: 05 May 2015
Invoice No.:EXP/92001577/17-18
ADC Attested invoice:30-01-2018
<table>
<tr><th>Batch No.</th><th>Quantity imported</th></tr>
<tr><td>MT00600118</td><td>1280kg</td></tr>
<tr><td>MT00610118</td><td>1280kg</td></tr>
<tr><td>MT00620118</td><td>1280kg</td></tr>
<tr><td>MT00630118</td><td>1160kg</td></tr>
</table>
</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>
<u>Empagliflozin Working Standard</u>
<table>
<tr><th>Source</th><th>Batch No.</th><th>Quantity imported</th><th>Date of declaration</th></tr>
<tr><td>Ruyuan HEC Pharm Co.</td><td>EGLZ-WS20161201</td><td>2g</td><td>09-07-2018</td></tr>
</table>
<u>Metformin HCL</u>
Commercial invoice no: 29829781
Copy of commercial invoice from USP for reference standards of Metformin HCl & impurity 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>
<u>Empagliflozin</u>
Firm has provided copy of GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd, China for Empagliflozin valid till 21-01-2019, issued by Shaoguan FDA.
<u>Metformin HCl</u>
Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd., West Godavari District, Andhra Pradesh, India has been submitted.
</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>
➢ The firm has submitted Vendor evaluation Form.
➢ Copy of Vendor Certification Questionnaire filled for M/s Ruyuan HEC Pharm Co., Ltd.
➢ Copy of Vendor Certification Questionnaire filled for M/s Wanbury Ltd., Dist. Raigad, Maharashtra State, India.
</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’s have been submitted, detailed as under:
<table>
<tr><th>API</th><th>Batch. #</th><th>Source</th></tr>
<tr><td>Empagliflozin</td><td>EGLZ-RD20171101A</td><td>HEC Ruyuan Pharm</td></tr>
<tr><td>Empagliflozin Working standard</td><td>EGLZ-WS201612101</td><td>HEC Ruyuan Pharm</td></tr>
<tr><td>Metformin HCL USP</td><td>MT00600118</td><td>USP</td></tr>
<tr><td>Metformin Related Compound A</td><td>R072Y0</td><td>USP</td></tr>
<tr><td>Melamine</td><td>G1M492</td><td>USP</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 of the excipients used in formulation from relevant manufacturers.
<table>
<tr><th>Excipient</th><th>Commercial Invoice</th></tr>
<tr><td>Maize Starch</td><td>Mak Kemikal, 400kg,</td></tr>
<tr><td>PVP K30</td><td>Mak Kemikal, 300kg</td></tr>
<tr><td>Aerosil 200</td><td>Mak Kemikal, 100kg</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>Opadry II white</td><td>Colorcon, 41.97 kg</td></tr>
<tr><td>Magnesium Stearate</td><td>Premium Chemicals, 200Kg</td></tr>
<tr><td>PVP Copovidone</td><td>Zhejiang Neo-Dankong Pharmaceutical, 10Kg</td></tr>
<tr><td>Black Currant</td><td>Far Eastern impex, Pakistan, Qty. 5kg</td></tr>
<tr><td>Dye, Red Iron oxide</td><td>Dawawala Chemical Corp.,50Kg</td></tr>
</table>
<table>
<tr><th>Excipient</th><th>Source</th><th>Batch No.</th></tr>
<tr><td>Copovidone</td><td>Boai NKY Pharmaceuticals, China</td><td>P170822002</td></tr>
<tr><td>Corn Starch</td><td>Gujarat Ambuja Exports, India</td><td>418</td></tr>
<tr><td>Colloidal Silicon Dioxide</td><td>Evonik</td><td>137070130</td></tr>
<tr><td>Magnesium Stearate</td><td>Huzhou City Linghu Xinwang Chemical Co, China</td><td>20180118</td></tr>
<tr><td>Opadry II white</td><td>Colorcon</td><td>DT661438</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 photocopy of following documents for development of Empag-M 12.5/500mg tablet
a. Development protocol.
b. Stability Study 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 Empag-M 5/1000mg tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>18SB-100-01</td><td>04-2018</td><td>1500 Tablets</td></tr>
<tr><td>18SB-101-02</td><td>04-2018</td><td>1500 Tablets</td></tr>
<tr><td>18SB-102-03</td><td>04-2018</td><td>1500 Tablets</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>18SB-100-01 18SB-101-02 18SB-102-03
Batch size: 1500 Tablets
Received for Stability: 200 Tablets
Balance: Nil (40C/75%rH)
Balance: 168 (30C/65%rH)</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.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has applied supplier’s method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.</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 specification & Test method.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
</table>

15.	Reports of stability studies of API from manufacturer.	**Empagliflozin** The firm has submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, 65±5%) Data of 03 Batches of API. **Metformin HCl** The firm has submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, 65±5%) Data of 03 Batches of API.
16.	Analysis reports for excipients used.	The firm has submitted copies of its own Analytical reports for all excipients used in product development.
17.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation. Therefore it is presumed that used inactive ingredients are compatible with active & also with each other and this is ensured by satisfactory results from formal stability studies.
18.	Record of comparative dissolution data.	pH 0.1N , Acetate buffer 4.5, Buffer 6.8.

Feature	Reference product	Genix Product
Brand name	Synjardy	
Batch No.	706521	18SB-100-01
Mfg. date	03-2018	04-2018

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three 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 GMP Inspection Report Date & Remarks**
404.	**M/s Genix Pharma Pvt. Ltd. Karachi.**	Empag-M Tablet 12.5mg/1000 mg Tablet Each film coated tablet contains: Empagliflozin.....12.5mg Metformin hydrochloride ……..1000mg (Anti Diabetic)	Form-5-D Dy. No: 30796 Dated.12-09-2018 Rs.50,000/- (12-09-2018) 2x7's; As per SRO.	USFDA Approved. Last GMP inspection conducted on 08-08-2017, and the report concludes that firm is operating at satisfactory level of compliance of GMP.
	Evaluation by PEC: Firm has claimed innovator's Specification.			

STABILITY STUDY DATA	
Drug	Each film coated tablet contains: Empagliflozin ……12.5mg Metformin hydrochloride ……..1000mg
Name of Manufacturer	M/s Genix Pharma Pvt. Ltd. Karachi.
Manufacturer of API	**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China
	Metformin hydrochloride: M/s Wanbury Ltd., India
API Lot No.	**Empagliflozin:** EGLZ-RD20171101A
	Metformin hydrochloride: MT00600118, MT00610118, MT00620118 MT00630118
Description of Pack (Container closure system)	Alu-Alu Blister Pack

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.	18SB-103-01	18SB-103-02	18SB-103-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	11-04-2018	11-04-2018	11-04-2018
No. of Batches	3		
Date of Submission	43218, 19-12-2018		

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.	Empagliflozin Firm has provided copy of valid GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd, China for Empagliflozin valid till 21-01-2019, issued by Shaoguan FDA.
		Metformin HCl Firm also provided copy of GMP certificate of M/s Wanbury Ltd., India for Metformin HCl valid till 28-07-2018 issued by Director, Drugs Control Administration, Government of Andhra Pradesh - India. Submit valid GMP certificate.
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

REQUEST OF EXEMPTION ROM 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 onsite inspection report of their product "Wymly Tablets 25 mg", which was conducted on 9th April, 2018. (Afternoon) and was presented in 281st meeting of Registration Board. Following observations were reported in the report: ✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA ✓ The firm has audit trail Reports on testing. ✓ Adequate monitoring and control are available for stability

<table>
<tr><td></td><td></td><td>chamber. Chambers are controlled and monitored through software 21CFR compliance.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>
EMPAGLIFLOZIN
➢ <u>Declaration by WIS Pharmtec Co. Ltd, China</u>
The firm has imported Empagliflozin API 750 g from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information.
Batch No.: EGLZ-RD20171101A
Mfg Date: 01-11-2017
➢ <u>Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China</u>
Invoice No. WIS170152
Quantity imported: 0.75 Kg
Date of import: 29-06-2016
ADC Attestation Date: 07-12-2017
Manufacturer: Ruyuan HEC Co. Pharm. Co. Ltd.
Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China.
Commercial invoice doesnot mention the batch no.

METFORMIN HCL
➢ <u>Details of ADC Attested invoice commercial Invoice by WanburyLtd., India</u>
Firm has imported Metformin HCl from M/s Wanbury Ltd., India and has approval from DRAP for import.
Date of Import: 05 May 2015
Invoice No.:EXP/92001577/17-18
ADC Attested invoice:30-01-2018
<table>
<tr><th>Batch No.</th><th>Quantity imported</th></tr>
<tr><td>MT00600118</td><td>1280kg</td></tr>
<tr><td>MT00610118</td><td>1280kg</td></tr>
<tr><td>MT00620118</td><td>1280kg</td></tr>
<tr><td>MT00630118</td><td>1160kg</td></tr>
</table>
</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>
<u>Empagliflozin Working Standard</u>
<table>
<tr><th>Source</th><th>Batch No.</th><th>Quantity imported</th><th>Date of declaration</th></tr>
<tr><td>Ruyuan HEC Pharm Co.</td><td>EGLZ-WS20161201</td><td>2g</td><td>09-07-2018</td></tr>
</table>
<u>Metformin HCL</u>
Commercial invoice no: 29829781
Copy of commercial invoice from USP for reference standards of Metformin HCl & impurity 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>
<u>Empagliflozin</u>
Firm has provided copy of GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd, China for Empagliflozin valid till 21-01-2019, issued by Shaoguan FDA.
<u>Metformin HCl</u>
➢ Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd., West Godavari District, Andhra Pradesh, India has been submitted.
</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>
➢ The firm has submitted Vendor evaluation Form.
➢ Copy of Vendor Certification Questionnaire filled for M/s Ruyuan HEC Pharm Co., Ltd.
➢ Copy of Vendor Certification Questionnaire filled for M/s
</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Wanbury Ltd., Dist. Raigad, Maharashtra State, India.</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's have been submitted, detailed as under:
<table>
<tr><th>API</th><th>Batch. #</th><th>Source</th></tr>
<tr><td>Empagliflozin</td><td>EGLZ-RD20171101A</td><td>HEC Ruyuan Pharm</td></tr>
<tr><td>Empagliflozin Working standard</td><td>EGLZ-WS201612101</td><td>HEC Ruyuan Pharm</td></tr>
<tr><td>Metformin HCL USP</td><td>MT00600118</td><td>USP</td></tr>
<tr><td>Metformin Related Compound A</td><td>R072Y0</td><td>USP</td></tr>
<tr><td>Melamine</td><td>G1M492</td><td>USP</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 of the excipients used in formulation from relevant manufacturers.
<table>
<tr><th>Excipient</th><th>Commercial Invoice</th><th></th></tr>
<tr><td>Maize Starch</td><td>Mak Kemikal, 400kg,</td><td></td></tr>
<tr><td>PVP K30</td><td>Mak Kemikal, 300kg</td><td></td></tr>
<tr><td>Aerosil 200</td><td>Mak Kemikal, 100kg</td><td></td></tr>
<tr><td>Opadry II white</td><td>Colorcon, 41.97 kg</td><td>DT661438</td></tr>
<tr><td>Magnesium Stearate</td><td>Premium Chemicals, 200Kg</td><td></td></tr>
<tr><td>PVP Copovidone</td><td>Zhejiang Neo-Dankong Pharmaceutical, 10Kg</td><td></td></tr>
<tr><td>Black Currant</td><td>Far Eastern impex, Pakistan, Qty. 5kg</td><td></td></tr>
<tr><td>Dye, Red Iron oxide</td><td>Dawawala Chemical Corp.,50Kg</td><td></td></tr>
</table>
<table>
<tr><td>Excipient</td><td>Source</td><td>Batch No.</td></tr>
<tr><td>Copovidone</td><td>Boai NKY Pharmaceuticals, China</td><td>P170822002</td></tr>
<tr><td>Corn Starch</td><td>Gujarat Ambuja Exports, India</td><td>418</td></tr>
<tr><td>Colloidal Silicon Dioxide</td><td>Evonik</td><td>137070130</td></tr>
<tr><td>Magnesium Stearate</td><td>Huzhou City Linghu Xinwang Chemical Co, China</td><td>20180118</td></tr>
<tr><td>Opadry II white</td><td>Colorcon</td><td>DT661438</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 photocopy of following documents for development of Empag-M 12.5/1000mg tablet
a. Development protocol.
b. Stability Study 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 Empag-M 5/1000mg tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>18SB-103-01</td><td>04-2018</td><td>1500 Tablets</td></tr>
</table></td></tr>
</table>

		18SB-104-02 | 04-2018 | 1500 Tablets 18SB-105-03 | 04-2018 | 1500 Tablets
11.	Record of remaining quantities of stability batches.	18SB-103-01, 18SB-104-02, 18SB-105-03 Batch size: 1500 Tablets Received for Stability: 200 Tablets Balance: Nil (40C/75%rH) Balance: 168 (30C/65%rH)
	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 photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions.
13.	Method used for analysis of API along with COA.	The firm has applied supplier's method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.
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 specification & Test method. • Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
15.	Reports of stability studies of API from manufacturer.	Empagliflozin The firm has submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, $65 \pm 5\%$) Data of 03 Batches of API. Metformin HCl The firm has submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, $65 \pm 5\%$) Data of 03 Batches of API.
16.	Analysis reports for excipients used.	The firm has submitted copies of its own Analytical reports for all excipients used in product development.
17.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation. Therefore it is presumed that used inactive ingredients are compatible with active & also with each other and this is ensured by satisfactory results from formal stability studies.
18.	Record of comparative dissolution data.	pH 0.1N , Acetate buffer 4.5, Buffer 6.8. **Feature** | **Reference product** | **Genix Product** Brand name | Synjardy | Batch No. | 605012 | 18SB-103-01 Mfg. date | 01-2018 | 04-2018
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three 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 GMP Inspection Report Date & Remarks**
405.	M/s Genix Pharma Pvt. Ltd. Karachi.	Empag-M Tablet 5mg/1000 mg Each film coated tablet contains: Empagliflozin .....5mg Metformin hydrochloride	Form-5-D Dy. No: 30794 Dated.12-09-2018 Rs.50,000/- (12-09-	USFDA Approved. Last GMP inspection conducted on 08-08-2017, and the report

		……..1000mg (Anti Diabetic)\ Innovator Specs.	2018) 2x7's; As per SRO.	concludes that firm is operating at satisfactory level of compliance of GMP.
	Evaluation by PEC: Firm has claimed innovator's Specification.			
STABILITY STUDY DATA				
Drug		Each film coated tablet contains: Empagliflozin ….....5mg Metformin hydrochloride ……..1000mg		
Name of Manufacturer		M/s Genix Pharma Pvt. Ltd. Karachi.		
Manufacturer of API		**Empagliflozin:** Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China		
		Metformin hydrochloride: M/s Wanbury Ltd., India		
API Lot No.		**Empagliflozin:** EGLZ-RD20171101A		
		Metformin hydrochloride: MT00600118, MT00610118, MT00620118 MT00630118		
Description of Pack (Container closure system)		Alu-Alu Blister Pack		
Stability Storage Condition		Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period		Real time: 6 months Accelerated: 6 months		
Frequency		Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6 (month)		
Batch No.		18SB-097-01	18SB-098-02	18SB-099-03
Batch Size		1500 tablets	1500 tablets	1500 tablets
Manufacturing Date		04-2018	04-2018	04-2018
Date of Initiation		11-04-2018	11-04-2018	11-04-2018
No. of Batches		3		
Date of Submission		39388, 30-11-2018		
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.		Empagliflozin Firm has provided copy of valid GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd, China for Empagliflozin valid till 21-01-2019, issued by Shaoguan FDA.	
			Metformin HCl Firm also provided copy of GMP certificate of M/s Wanbury Ltd., India for Metformin HCl valid till 28-07-2018 issued by Director, Drugs Control Administration, Government of Andhra Pradesh - India. Submit valid GMP certificate.	
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		Yes	

<table>
<tr><td></td><td>and stamp) for ensuring authenticity of data / documents.</td><td></td></tr>
<tr><td>7.</td><td>Commitment to continue real time stability study till assigned shelf life of the product.</td><td>Yes</td></tr>
<tr><td>8.</td><td>Commitment to follow Drug Specification Rules, 1978.</td><td>Yes</td></tr>
<tr><td colspan="3">REMARKS OF EVALUATOR</td></tr>
<tr><td colspan="3">REQUEST OF EXEMPTION ROM ON SITE INSPECTION</td></tr>
<tr><td colspan="3">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:</td></tr>
<tr><td colspan="3">Administrative Portion</td></tr>
<tr><td>1.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has referred to onsite inspection report of their product “Wymly Tablets 25 mg”, which was conducted on 9th April, 2018. (Afternoon) and was presented in 281st meeting of Registration Board.
Following observations were reported in the report:
✓ The HPLC software is 21CFR compliant and having certificates of Compliance by USFDA
✓ The firm has audit trail Reports on testing.
✓ Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software 21CFR compliance.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>
<u>EMPAGLIFLOZIN</u>
➢ <u>Declaration by WIS Pharmtec Co. Ltd, China</u>
The firm has imported Empagliflozin API 750 g from M/s WIS Pharmtec Co. Ltd, China and the declaration includes the following information.
Batch No.: EGLZ-RD20171101A
Mfg Date: 01-11-2017
➢ <u>Details of ADC attested commercial Invoice by WIS Pharmtec Co. Ltd, China</u>
Invoice No. WIS170152
Quantity imported: 0.75 Kg
Date of import: 29-06-2016
ADC Attestation Date: 07-12-2017
Manufacturer: Ruyuan HEC Co. Pharm. Co. Ltd. Xiaba Development Zone, Ruyuan County, Shaoguan City, Guangdong Province, China.
Commercial invoice doesnot mention the batch no.

<u>METFORMIN HCL</u>
➢ <u>Details of ADC Attested invoice commercial Invoice by WanburyLtd., India</u>
Firm has imported Metformin HCl from M/s Wanbury Ltd., India and has approval from DRAP for import.
Date of Import: 05 May 2015
Invoice No.:EXP/92001577/17-18
ADC Attested invoice:30-01-2018
<table>
<tr><th>Batch No.</th><th>Quantity imported</th></tr>
<tr><td>MT00600118</td><td>1280kg</td></tr>
<tr><td>MT00610118</td><td>1280kg</td></tr>
<tr><td>MT00620118</td><td>1280kg</td></tr>
<tr><td>MT00630118</td><td>1160kg</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><u>Empagliflozin Working Standard</u>
<table>
<tr><th>Source</th><th>Batch No.</th><th>Quantity imported</th><th>Date of declaration</th></tr>
<tr><td>Ruyuan HEC Pharm Co.</td><td>EGLZ-WS201 61201</td><td>2g</td><td>09-07-2018</td></tr>
</table>
<u>Metformin HCL</u>
Commercial invoice no: 29829781
Copy of commercial invoice from USP for reference standards of Metformin HCl & impurity 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><u>Empagliflozin</u>
Firm has provided copy of GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd, China for Empagliflozin valid till 21-01-2019, issued by Shaoguan FDA.
<u>Metformin HCl</u>
Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>➢ The firm has submitted Vendor evaluation Form.
➢ Copy of Vendor Certification Questionnaire filled for M/s Ruyuan HEC Pharm Co., Ltd.
➢ Copy of Vendor Certification Questionnaire filled for M/s Wanbury Ltd., Dist. Raigad, Maharashtra State, India.</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’s have been submitted, detailed as under:
<table>
<tr><th>API</th><th>Batch. #</th><th>Source</th></tr>
<tr><td>Empagliflozin</td><td>EGLZ-RD20171101A</td><td>HEC Ruyuan Pharm</td></tr>
<tr><td>Empagliflozin Working standard</td><td>EGLZ-WS201612101</td><td>HEC Ruyuan Pharm</td></tr>
<tr><td>Metformin HCL USP</td><td>MT00600118</td><td>USP</td></tr>
<tr><td>Metformin Related Compound A</td><td>R072Y0</td><td>USP</td></tr>
<tr><td>Melamine</td><td>G1M492</td><td>USP</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 of the excipients used in formulation from relevant manufacturers.
Commercial Invoice of Colorcon required.
<table>
<tr><th>Excipient</th><th>Commercial Invoice</th><th></th></tr>
<tr><td>Maize Starch</td><td>Mak Kemikal, 400kg,</td><td></td></tr>
<tr><td>PVP K30</td><td>Mak Kemikal, 300kg</td><td></td></tr>
<tr><td>Aerosil 200</td><td>Mak Kemikal, 100kg</td><td></td></tr>
<tr><td>Opadry II white</td><td>Colorcon, COA not commercial invoice</td><td>DT661 438</td></tr>
<tr><td>Magnesium Stearate</td><td>Premium Chemicals, 200Kg</td><td></td></tr>
<tr><td>PVP Copovidone</td><td>Zhejiang Neo-Dankong Pharmaceutical, 10Kg</td><td></td></tr>
<tr><td>Yellow Iron Oxide</td><td>Dawawala Chemical Coorporation, 5 kg</td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>Excipient</th><th>Source</th><th>Batch No.</th></tr>
<tr><td>Copovidone</td><td>Boai NKY Pharmaceuticals, China</td><td>P170822002</td></tr>
<tr><td>Corn Starch</td><td>Gujarat Ambuja Exports, India</td><td>418</td></tr>
<tr><td>Colloidal Silicon Dioxide</td><td>Evonik</td><td>137070130</td></tr>
<tr><td>Magnesium Stearate</td><td>Huzhou City Linghu Xinwang Chemical Co, China</td><td>20180118</td></tr>
<tr><td>Opadry II white</td><td>Colorcon</td><td>DT661438</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 photocopy of following documents for development of Empag-M 5/1000mg tablet
c. Development protocol.
d. Stability Study 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 Empag-M 5/1000mg tablets such as.
<table>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>18SB-097-01</td><td>04-2018</td><td>1500 Tablets</td></tr>
<tr><td>18SB-098-02</td><td>04-2018</td><td>1500 Tablets</td></tr>
<tr><td>18SB-099-03</td><td>04-2018</td><td>1500 Tablets</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>18SB-097-01,18SB-098-02,18SB-099-03
Batch size: 1500 Tablets
Received for Stability: 200 Tablets
Balance: Nil (40C/75%rH)
Balance: 168 (30C/65%rH)</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.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has applied supplier’s method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.</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 specification & Test method.
• Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
</table>

15.	Reports of stability studies of API from manufacturer.	Empagliflozin The firm has submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, 65±5%) Data of 03 Batches of API. Metformin HCl The firm has submitted copies of reports of 06 Months Accelerated and 24 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, 65±5%) Data of 03 Batches of API.
16.	Analysis reports for excipients used.	The firm has submitted copies of its own Analytical reports for all excipients used in product development.
17.	Drug-excipients compatibility studies.	• Not submitted by the firm. Firm has stated that composition of developed product is similar to innovator's product formulation. Therefore it is presumed that used inactive ingredients are compatible with active & also with each other and this is ensured by satisfactory results from formal stability studies.
18.	Record of comparative dissolution data.	pH 0.1N , Acetate buffer 4.5, Buffer 6.8.

Feature	**Reference product**	**Genix Product**
Brand name	Synjardy	
Batch No.	802167	18SB-097-01
Mfg. date	02-2018	04-2018

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three 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)**
406.	"M/s Genix Pharma Pvt Ltd, 44-45/B, Korangi Creek Raod, Karachi"	Empag-M Tablet 5mg/500 mg "Each film coated tablet contains: Empagliflozin …… 5mg Metformin HCl ….. 500mg" (Antidiabetic)	Form-5D Dy. No 30793 dated 12-09-2018 Rs.50,000/- Dated 12-09-2018 10's, 14's20's, 28's & 30's As per SRO	Approved by USFDA Last GMP inspection conducted on 16-02-2018concluding satisfactory level of cGMP compliance..	

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Empag-M Tablet 5mg/500 mg
Name of Manufacturer	M/s Genix Pharma Pvt Ltd, 44-45/B, Korangi Creek Raod, Karachi
Manufacturer of API	Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China Metformin HCl: M/s Wanbury Ltd., Dist. Raigad, Maharashtra State., India
API Lot No.	Empagliflozin: EGLZ-RD20171101A Metformin HCl: MT00600118
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton

Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	18SB-093-01	18SB-095-02	18SB-096-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	11-04-2018	11-04-2018	11-04-2018
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.	**Empagliflozin:** Copy of GMP certificate (2017029) issued by M/s Shaoguan Food & Drug Administration, valid upto 21-01-2019 for M/s Ruyuan HEC Pharm Co., Ltd. **Metformin HCl:** Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India
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.	**Empagliflozin:** Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad of Empagliflozin has been attached. **Batch No.** / **Invoice No.** / **Quantity Imported.** EGLZ-RD20171101A / WIS170152 / 750gm **Metformin HCl:** Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad of Metformin HCl has been attached.
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.

<table>
<tr><th colspan="3">REQUEST OF EXEMPTION FROM ON SITE INSPECTION</th></tr>
<tr><td colspan="3">Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Empag-M Tablets tablets vide Letter no. RA/223//18, dated 21-12-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
(Date of submission: 26-12-2018 vide diary no. 43816)</td></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>Firm has referred to onsite inspection report of their product “Wymly 25mg Tablets”, which was conducted on 9th Apr, 2018 and was presented in 281st meeting of Registration Board held on 11th – 13th April, 2018.
Registration Board decided to approve registration of “Wymly 25mg Tablets (Tenofovir alafenamide as fumarate)Tablets
Following observations were reported in the report:
i. The HPLC software is 21CFR compliant.
ii. The firm has audit trail Reports on testing.
iii. Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software 21CFR compliance</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Empagliflozin:
Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 07-12-2017 for the import of Empagliflozin has been attached.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported.</th></tr>
<tr><td>EGLZ-RD20171101A</td><td>WIS170152</td><td>750gm</td></tr>
</table>
Metformin HCl:
Copy of Commercial Invoice signed & stamped by ADC DRAP, Islamabad dated 30-01-2018 for the import of Metformin HCl has been attached.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Empagliflozin:
Firm has submitted a copy of declaration dated 09-07-2018 from M/s Ruyuan HEC Pharm Co., Ltd. China, stating submission of 2gm Empagliflozin working standard (batch# EGLZ-WS201612101) to M/s Genix Pharma (Pvt.) Ltd.
Metformin HCl:
Copy of commercial invoice from USP for reference standards of Metformin HCl & impurity 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>Empagliflozin:
Copy of GMP certificate (2017029) issued by M/s Shaoguan Food & Drug Administration, valid upto 21-01-2019 for M/s Ruyuan HEC Pharm Co., Ltd.
Metformin HCl:
Copy of GMP certificate issued by DCA Andhra Pradesh valid upto 05-02-2022 for M/s Wanbury Ltd.,West Godavari District, Andhra Pradesh, India</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted copy of SOP for Vendor Certification.
• Copy of Vendor Certification Questionnaire filled for M/s Ruyuan HEC Pharm Co., Ltd.
• Copy of Vendor Certification Questionnaire filled for M/s Wanbury Ltd., Dist. Raigad, Maharashtra State, India.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted certificate of analysis for Empagliflozin, working standard for Empagliflozin and Metformin HCl.
USP certificates for reference standard &impurity standards of Metformin HCl has been submitted.</td></tr>
</table>

<table>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the 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>The firm has submitted photocopy of List of qualified staff (4 members) 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 photocopy of following documents for development of Empag-M 5/500mg tablet
a. Development protocol.
b. Stability Study 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 Empag-M 5/500mg tablets such as.

<table><tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr><tr><td>18SB-093-01</td><td>04-2018</td><td>1500 Tablets</td></tr><tr><td>18SB-095-02</td><td>04-2018</td><td>1500 Tablets</td></tr><tr><td>18SB-096-03</td><td>04-2018</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 sample utilization record for three trial batches kept in stability chambers for accelerated & long term stability studies.</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, COA and analytical record including chromatograms for both Empagliflozin & Metformin HCl.</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 Empag-M 5/500 mg tablets along with Stability Study Report of stability batches, lab reports, raw data sheets etc.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Empagliflozin: The firm has submitted stability studies reports for both Accelerated (40°C ± 2°C / 75% ± 5%RH) for 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 24 months from manufacturer.
Metformin HCl:
The firm has submitted stability studies reports for both Accelerated (40°C ± 2°C / 75% ± 5%RH) for 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 72 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 Empag-M 5/500 mg tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• Not submitted by the firm.
• Firm has stated that composition of developed product is similar to innovator’s product formulation. Therefore it is presumed that used inactive ingredients are compatible with active & also with each other and this is ensured by satisfactory results from formal stability studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative Dissolution Profile protocol &</td></tr>
</table>

reports. The details of reference product & Sample product are as follows:

Feature	Reference product	Product of M/s Genix
Brand name	Synjardy 5/500mg tablet	Empag-M 5/500mg tablet
Batch No.	803151	18SB-093-01
Expiry date	02-2021	--

- Comparative dissolution studies have been performed in following mediums:
  a. 0.1N HCl buffer
  b. pH 4.5 Acetate buffer
  c. pH 6.8 Phosphate buffer
- Firm has submitted relevant chromatograms and results for the CDP study showing acceptable f2 values.

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

Remarks of Evaluator:

- Raw material analytical test method of Empagliflozin submitted by firm differs from supplier's testing method as per following details:

Test parameter	Method of M/s Ruyuan HEC	Method of M/s Genix
Detector wavelength of HPLC for Assay test	210	223

- Clarify why potency adjustment not done for Empagliflozin and Metformin as assay is 99.20% and 99.69%, respectively.
- Test for "Content of Uniformity" for Empagliflozin has not been performed for all three stability batches.

Upon communication of above observation vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 18-01-2019. Firm responded as under vide its letter no. RA/038/19 (dated 12-02-2019):

- Empagliflozin shows its maxima at 223nm. Reference spectrum of Empagliflozin is attached. Revised method from supplier of Empagliflozin with wavelength at 223nm has been submitted.
- Test for "Content of Uniformity" for Empagliflozin has been performed for all three stability batches at the most recent time point of long term stability studies.
- Firm has submitted that "we have revised the SOP of Product development for potency adjustment of Active Raw materials and potency will be adjusted upto 100% for all trial products as we dispense after adjustment the potency upto 100% for commercial batches. It I sour practice for all API dispense after potency adjustment for commercial products."

Decision:Registration Board decided to approve registration of "Empag-M Tablet 5mg/500mg (Empagliflozin/Metformin hydrochloride), Empag-M Tablet 5mg/1000mg (Empagliflozin/Metformin hydrochloride), Empag-M Tablet 12.5mg/1000mg (Empagliflozin/Metformin hydrochloride) and Empag-M Tablet 12.5mg/500mg (Empagliflozin/Metformin hydrochloride) by M/s M/s Genix Pharma Pvt. Ltd. Karachi. Manufacturer will place first three production batches of all 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 GMP Inspection Report Date & Remarks
407.	M/s Neutro Pharma (Pvt.) Ltd. Lahore, Pakistan.	Dacla 60mg tablets Each film coated tablet contains:- Daclatasvir dihydrochloride eq. to Daclatasvir… 60mg (NS5A Inhibitor)	Form 5 Dy.# 35251 dated 23-10-2018 Rs. 20,000/- 23-10-2018 28's, As per SRO	Approved by USFDA Last GMP inspection report dated 18-07-2017 concluding that firm has maintained a fair level of GMP compliance.
	Evaluation by PEC: Firm has submitted 6 months accelerated and Long term stability studies detailed as under:			

STABILITY STUDY DATA			
Drug	Dacla 60mg tablets		
Name of Manufacturer	M/s Neutro Pharma (Pvt.) Ltd. Lahore, Pakistan.		
Manufacturer of APIs	M/s Ruyuan HEC Pharm, Guangdong, China.		
API Lot No.	DSV-RD20106101		
Description of Pack (Container closure system)	Unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 month Real Time: 0,3,6 month		
Batch No.	HTB 003	HTB 004	HTB 005
Batch Size	2222 tablets	2222 tablets	2222 tablets
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	02-2018	02-2018	02-2018
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.	Copy of GMP certificate issued by Shaoguan Food and Drug Administration valid upto 17-06-2018.
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.	Yes

Documents confirming import of API etc.	Copy of commercial invoice attested by ADC DRAP, Lahore dated 11-07-2017.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Dissolution method submitted by you in finished product testing method is different from that recommended by USFDA.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of 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 onsite inspection reports of their product "NUVALDI Tablets 400mg (Sofosbuvir)", which was presented in 281st meeting of Registration Board wherein Registration Board decided to approve registration of "NUVALDI Tablets 400mg (Sofosbuvir) by M/s. Neutro Pharma (Pvt.) Ltd., Lahore. Following observations were recorded in the report: • Firm have used HPLC system from KNAUR (Germany) for testing of stability batches. Software ClarityChrom® which is 21CFR Compliant. 02 Users (QCM - Mr. Shahzad and Analyst - Ms. Sumbul) have access to the HPLC software as observed at the time of inspection. However the analyst had access to QCM's account as well. The firm was advised to change this practice at once. • Firm have shown audit trail reports on stability study testing.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial invoice (invoice# WIS70072) dated 28-06-2017, from M/s WIS Pharmatech Co., Ltd, China in the name of M/s Neutro Pharma (Pvt.) Ltd. Lahore for Daclatasivr dihydrochloride. The said invoice has been attested by AD DRAP (I&E) Lahore, dated 14-07-2014.
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted a copy of a label declaring content as "Daclatasvir reference standard" with Batch# PRS-17023 & quantity 100mg. Manufacturer is M/s Ruyuan HEC Pharm Co., Ltd. China. No document for impurity standard has been submitted.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Shaoguan Food and Drug Administration valid upto 17-06-2018.
5.	Mechanism for Vendor pre-qualification	• The firm has submitted SOP for Vendor Supplier Evaluation.
6.	Certificate of analysis of the API, reference standards and impurity standards	Photocopy of COA of Daclatasivr dihydrochloride with Batch No. DSV-RD201706101 by M/s Ruyuan HEC Pharm Co., Ltd. China is submitted.

Batch No.	Mfg. Date	Quantity Imported.
DSV-RD201706101	09-06-2017	1.5Kgs

<table>
<tr><td></td><td></td><td>Reference standards: Qualification report of reference standard of Batch No. PRS-17023 R/RD/60121118 by M/s Ruyuan HEC Pharm Co., Ltd. China is submitted.
No document for impurity standard has been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development.</td><td>Submitted</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 involved in product development comprising of 5 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 Real time & Accelerated Stability along with manufacturing protocol for all three trial batches of Dacla 60mg tablet.</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 of three stability batches of Dacla 60mg tablet, such as.
<table>
<tr><th colspan="3">Dacla 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>HTB-003</td><td>01-2018</td><td>2222 Tablets</td></tr>
<tr><td>HTB-004</td><td>01-2018</td><td>2222 Tablets</td></tr>
<tr><td>HTB-005</td><td>01-2018</td><td>2222 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">Dacla 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>HTB-003</td><td>280</td></tr>
<tr><td>HTB-004</td><td>252</td></tr>
<tr><td>HTB-005</td><td>308</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 Accelerated Long term 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 COA & testing procedures for Daclatasvir dihydrochloride from M/s Ruyuan HEC Pharm, China, along with relevant FTIR spectrums and chromatograms for the API analysis.</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 Dacla 60mg 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 for both Accelerated (40°C ± 2°C / 75% ± 5%RH) for 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 24 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 Dacla tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has submitted analytical record for drug excipient compatibility studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative Dissolution reports. The details of reference product & Sample product are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Neutro</th></tr>
<tr><td>Brand name</td><td>Mydacla 60mg of</td><td>Dacla 60mg tablet</td></tr>
</table></td></tr>
</table>

		m/s Mylan India • Comparative dissolution studies have been performed in 0.1M HCl buffer. • Firm has submitted relevant UV spectrums and results for the CDP study. • Firm has performed CDP in one buffer medium only for 6 tablets only, whereas as per guidelines CDP shall be performed in three dissolution mediums using 12 units each of reference and sample product.
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

Remarks of Evaluator:

Observation	Response
Submitted digital data logging record of accelerated stability chamber shows fall in humidity measurement from 70% for the time period dated 06-03-2018 to 23-03-2018 as well as in the month of April, 2018 7 August, 2018. Clarification shall be submitted in this regard	Firm has replied as under: **"**It is clarified that the product was placed for accelerated stability studies at 40°C ± 2°C / 75% ± 5%RH. During the said period of time when humidity ranges were out of limit, the climate chamber of accelerated stability studies was out of order and the product was shifted to a parallel accelerated stability chamber which was being operated at the same conditions of temperature and humidity (40°C ± 2°C / 75% ± 5%RH) to avoid any effect on the study. So, it is assured that throughout the accelerated stability period, the product was exposed to optimum conditions of temperature and humidity for accelerated stability studies."
Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs of API analysis by M/s Neutro Pharma (Pvt.) Ltd. Lahore shall be submitted.	As per submitted analytical record for API analysis, firm has not applied supplier's method of analysis for Assay analysis since the elution program mentioned in supplier's method of analysis is gradient with run time of 35 minutes, whereas submitted chromatograms show run time of only 10 minutes.
Relevant analytical record i.e., chromatograms, raw data sheets for dissolution analysis for the complete stability studies have not been submitted.	Firm has submitted UV spectrums and raw data sheets for the dissolution analysis for the complete stability studies.
Finished product testing method mentions HPLC method for dissolution analysis whereas CDP samples have been analysed by UV spectrophotometric method.	Firm has stated that "Practically we used UV method for dissolution test, but mistakenly not written in SOP while HPLC method was lodged. We have rectified and providing you UV method for dissolution test in SOP for Declatasvir 60mg tablet. Next time we shall try to avoid such mistakes.
Firm has performed CDP in one buffer medium only for 6 tablets only, whereas as per guidelines CDP shall be performed in three dissolution mediums using 12 units each of reference and sample product.	Firm has submitted new data for CDP in one buffer of 0.1N HCl, using 12 tablets each of both reference product (Mydacla) and the trial product. F2 factor = 78.42 has been calculated by firm for the said CDP study.

- Dissolution method submitted by firm in finished product testing method is different from that recommended by USFDA in terms of Dissolution medium since firm has used 0.1M HCl while USFDA has recommended Phosphate Buffer, pH 6.8 with 0.75% Brij 35, as dissolution medium.
- The dossier has been submitted with brand name of "Dacla 60mg tablets", whereas most of the stability studies have been performed with Product name as Hepadec tablet.

Decision: Registration Board deferred the case for following reasons:

- **Documeneted evidence for the activity of shifting the samples of applied product to a parallel accelerated stability chamber, during the period when humidity ranges were out of limit for the parent Accaelerated stability studies chamber.**
- **Performance of dissolution test on the next time point of long term stability studies as per USFDA recommended method for all three stability 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)
408.	M/s Saffron Pharmaceuticals Pvt Ltd., 19-Km, Sheikhupura Road, Faisalabad	Xpedia-Met 12.5mg/500mg Tablets "Each film coated tablet contains: Alogliptin as benzoate …… 12.5mg Metformin HCl .. 500mg" (Antidiabetic)	Form-5D (Duplicate) Dy. dated 06-03-2015 Rs.50,000/- Dated 03-04-2015 (Photocopy attested by ABL spinning mills Faislabad) 30's/ Rs. 650/-	Approved by USFDA Last GMP inspection conducted on 13-10-2017recommending renewal of DML.	

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Xpedia-Met 12.5mg/500mg Tablets		
Name of Manufacturer	M/s Saffron Pharmaceuticals Pvt Ltd., 19-Km, Sheikhupura Road, Faisalabad		
Manufacturer of API	**Alogliptin Benzoate**: M/s Ruyuan HEC Pharm Co., Ltd. China **Metformin HCl**: M/s IPCA Lab. Aurangabad, India		
API Lot No.	Alogliptin benzoate: $AGLT_{II}$-201608101U Metformin HCl: 17322ML 2RMI		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3,6,9 7 12(months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	T-002	T-003	T-004
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	07-2017	08-2017	09-2017
Date of Initiation	02-08-2017	20-09-2017	06-10-2017
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

	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.	Firm has submitted copy of GMP certificate of **Alogliptin Benzoate** for M/s Ruyuan HEC Pharm Co Ltd. China Issued by Shaoguan Food and Drug Administration China valid upto 18-12-2019. Firm has submitted copy of GMP Certificate (certificate no. GMP/17/2014-157-3) of **Metformin** for M/s IPCA Lab. Aurangabad, India Issued by FDA Maharashtra State Aurangabad dated 28-07-2014. Validity of certificate is not evident for submitted document.
	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.	Yes
	Documents confirming import of API etc.	**Alogliptin Benzoate** Firm has submitted copy of ADC attested invoice (Invoice# PH60093) confirming import of 1.5 Kg **Alogliptin** from WIS Pharmatech. The invoice was cleared on 08.11.2016. **Metformin** Firm has submitted copy of ADC attested invoice confirming import of 500 Kg **Metformin HCl** from IPCA Lab. Ltd., India. The invoice was cleared on 15-12-2016.
	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
	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)
409.	M/s Saffron Pharmaceuticals Pvt Ltd., 19-Km, Sheikhupura Road, Faisalabad	Xpedia-Met 12.5mg/1000mg Tablets "Each film coated tablet contains: Alogliptin a sbenzoate …… 12.5mg Metformin HCl....1000mg (Antidiabetic)	Form-5D (Duplicate) dated 06-03-2015 Rs.50,000/- Dated 03-04-2015 (Photocopy attested by ABL spinning mills Faisalabad) 30's/ Rs. 650/-	Approved by USFDA Last GMP inspection conducted on 13-10-2017 recommending renewal of DML.	

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Xpedia-Met 12.5mg/500mg Tablets
Name of Manufacturer	M/s Saffron Pharmaceuticals Pvt Ltd., 19-Km, Sheikhupura Road, Faisalabad
Manufacturer of API	Alogliptin benzoate: M/s Ruyuan HEC Pharm Co., Ltd. China Metformin HCl: M/s IPCA Lab. Aurangabad, India
API Lot No.	Alogliptin benzoate: $AGLT_{II}$-201608101U Metformin HCl: 17322ML 2RMI
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months
Frequency	Real Time: 0,3,6,9 & 12 (months) Accelerated: 0,1,3 & 6 (months)

Batch No.	T-002	T-003	T-004
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	10-2017	12-2017	12-2017
Date of Initiation			
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

	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.	Firm has submitted copy of GMP certificate of **Alogliptin Benzoate** for M/s Ruyuan HEC Pharm Co Ltd. China Issued by Shaoguan Food and Drug Administration China valid upto 18-12-2019. Firm has submitted copy of GMP Certificate (certificate no. GMP/17/2014-157-3) of **Metformin** for M/s IPCA Lab. Aurangabad, India Issued by FDA Maharashtra State Aurangabad dated 28-07-2014. Validity of certificate is not evident for submitted document.
	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.	Yes
	Documents confirming import of API etc.	**Alogliptin Benzoate** Firm has submitted copy of ADC attested invoice (Invoice# PH60093) confirming import of 1.5 Kg **Alogliptin** from WIS Pharmatech. The invoice was cleared on 08.11.2016. **Metformin** Firm has submitted copy of ADC attested invoice confirming import of 500 Kg **Metformin HCl** from IPCA Lab. Ltd., India. The invoice was cleared on 15-12-2016.
	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
	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.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Xpedia Met 12.5/500mg Tablets & Xpedia-Met 12.5mg/1000mg vide Letter no. Saf/018/426 & Saf/018/427 respectively dated 19-12-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
(Date of submission: 21-12-2018 vide diary no. 43534 & 43535)

Administrative Portion

1.	Reference of last onsite panel	Firm has referred to onsite inspection report of their product

	inspection for instant dosage form conducted during last two years.	Saffaldi Tablet 400mg (Sofosbuvir), which was conducted on 8th January, 2018 and was presented in 279th meeting of Registration Board held on 28th February-2nd March, 2018. Following two observations were reported in the report: • The firm has used two HPLC systems in the stability studies of Saffaldi 400mg tablet details of which are as under: i. Schimadzu Lab solution (Equipment ID: QC-75) ii. Schimadzu LC solution (Equipment ID: QC-101) • Firm has demonstrated audit trail reports for the submitted stability studies. The relevant log books for stability studies were also verified. • The firm has stability chambers for accelerated and real time stability studies with uninterrupted power supply and digital data loggers. Records of digital data logger for both chambers were demonstrated.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Alogliptin Benzoate** Firm has submitted copy of ADC attested invoice (Invoice# PH60093) confirming import of 1.5 Kg **Alogliptin** from WIS Pharmatech. The invoice was cleared on 08.11.2016. **Metformin** Firm has submitted copy of ADC attested invoice confirming import of 500 Kg **Metformin HCl** from IPCA Lab. Ltd., India. The invoice was cleared on 15-12-2016.
3.	Documents for the procurement of reference standard and impurity standards.	Not submitted. Firm has stated that manufacturers have not provided impurity.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of **Alogliptin Benzoate** for M/s Ruyuan HEC Pharm Co Ltd. China Issued by Shaoguan Food and Drug Administration China valid upto 18-12-2019. Firm has submitted copy of GMP Certificate (certificate no. GMP/17/2014-157-3) of **Metformin** for M/s IPCA Lab. Aurangabad, India Issued by FDA Maharashtra State Aurangabad dated 28-07-2014. Validity of certificate is not evident for submitted document.
5.	Mechanism for Vendor pre-qualification.	Firm has submitted copy of SOPs for vendor qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards.	The firm has submitted certificates of analysis for Alogliptin Benzoate & Metformin HCl.COAs of reference standard has been submitted while COA of any impurity has not been 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
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted photocopy of List of qualified staff (2 members) involved in Research & Development department.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of following documents **a.** SOP for Pharmaceutical Product Development protocol. **b.** SOP for conducting stability studies.

<table>
<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 Xpedia-Met 12.5/500mg &Xpedia-Met 12.5/1000mg tablets such as.
<table>
<tr><th colspan="3">Xpedia-Met 12.5/500mg tablets</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>T-002</td><td>07-2017</td><td>1500 Tablets</td></tr>
<tr><td>T-003</td><td>09-2017</td><td>1500 Tablets</td></tr>
<tr><td>T-004</td><td>09-2017</td><td>1500 Tablets</td></tr>
<tr><th colspan="3">Xpedia-Met 12.5/1000mg tablets</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>T-002</td><td>10-2017</td><td>1500 Tablets</td></tr>
<tr><td>T-003</td><td>12-2017</td><td>1500 Tablets</td></tr>
<tr><td>T-004</td><td>12-2017</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 sample utilization record for three trial batches kept in stability chambers long term stability studies.
<table>
<tr><th colspan="2">Xpedia-Met 12.5/500mg tablets</th></tr>
<tr><th>Batch No.</th><th>Remaining quantities</th></tr>
<tr><td>T-002</td><td>254 Tablets</td></tr>
<tr><td>T-003</td><td>280 Tablets</td></tr>
<tr><td>T-004</td><td>192 Tablets</td></tr>
<tr><th colspan="2">Xpedia-Met 12.5/1000mg tablets</th></tr>
<tr><th>Batch No.</th><th>Remaining quantities</th></tr>
<tr><td>T-002</td><td>330 Tablets</td></tr>
<tr><td>T-003</td><td>330 Tablets</td></tr>
<tr><td>T-004</td><td>280 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>The firm has submitted photocopies of digital printouts for Real Time conditions only and that also does not cover the complete period of stability studies since submitted data is for January 2018 & February 2018 only.</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, COA and for both Alogliptin benzoate & Metformin HCl along with relevant analytical record.</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 Xpedia-Met 12.5/500mg tablets & Xpedia-Met 12.5/500mg tablets 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>Alogliptin benzoate: The firm has submitted stability studies reports for both Accelerated (40°C ± 2°C / 75% ± 5%RH) for 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 24 months from manufacturer.
Metformin HCl:
The firm has submitted stability studies reports for both Accelerated (40°C ± 2°C / 75% ± 5%RH) for 6 months & Long term (30°C ± 2°C / 65% ± 5%RH) conditions for 60 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 Xpedia-Met tablets.</td></tr>
</table>

<table>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Firm has submitted drug excipient compatibility studies by using binary mixtures of both APIs with all excipients and determination of %age content by HPLC analysis</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>Feature</th><th>Reference product</th><th>Product of M/s Genix</th></tr>
<tr><td>Brand name</td><td>Vipdomet 12.5/500mg tablet</td><td>Xpedia-Met 12.5/500mg tablet</td></tr>
<tr><td>Batch No.</td><td>1393181</td><td>T-002</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
a. pH 1.2 buffer
b. pH 4.5 Acetate buffer
c. pH 6.8 Phosphate buffer
• Firm has submitted results for the CDP study showing acceptable f2 values.</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:
• Dissolution test mentioned in submitted Standard Analytical Procedure and Xpedia-Met 12.5/500mg tablet (Document# QC/AP/FG/198) & of Xpedia-Met 12.5/1000mg tablet (Document# QC/AP/FG/208) differs from USFDA recommended method in terms of time, since USFDA has recommended 30 minutes whereas firm has applied 45 minutes.
• The firm has submitted photocopies of digital printouts for Real Time conditions only and that also does not cover the complete period of stability studies since submitted data is for January 2018 & February 2018 only.</td></tr>
<tr><td colspan="3">Decision: Deferred for following observations:
• Dissolution test mentioned in submitted Standard Analytical Procedure and Xpedia-Met 12.5/500mg tablet (Document# QC/AP/FG/198) & of Xpedia-Met 12.5/1000mg tablet (Document# QC/AP/FG/208) differs from USFDA recommended method in terms of time, since USFDA has recommended 30 minutes whereas firm has applied 45 minutes.
• The firm has submitted photocopies of digital printouts for Real Time conditions only and that also does not cover the complete period of stability studies since submitted data is for January 2018 & February 2018 only</td></tr>
</table>

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)
410	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"	Velocity tablets 60mg "Each film coated tablet contains: Ticagrelor….60mg" (Antithrombotic drugs)	Form-5D Dy. No 42034 dated 07-12-2018 Rs.20,000/- Dated 07-12-2018 2x10's, 6 x 10's, 3 x 10's, 4x7's, 2x14's, 28's: As per SRO	Approved by USFDA Anplag by M/s PharmEvo GMP certificate issued on the basis of inspection conducted on 10-10-2018 & 17-10-2018.	
STABILITY STUDY DATA SUBMITTED INITIALLY					

Drug	Velocity Tablets 60mg		
Name of Manufacturer	M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad		
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd, Z/103/I, Dahej SEZ Part-II, Opposite to GCPTTL, Dahej Gujrat		
API Lot No.	82160976		
Description of Pack (Container closure system)	Alu-Alu blister pack		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months		Accelerated: 6 months
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months)		Real Time: 0, 3, 6 (Months)
Batch No.	Trial#01	Trial#02	Trial#03
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	12-2017	12-2017	12-2017
Date of Initiation	27-12-2017	27-12-2017	27-12-2017
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.	Firm has submitted copy of GMP certificate (No. 16061165) dated 27-06-2016 issued by Food and Drugs control Administration Gujrat State India.
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.	Firm has submitted following • Copy of form 6 dated 16-05-2017, confirming license to import of M/s Scotmann with M/s Glenmark Pharmaceuticals Ltd, Z/103/I, Dahej SEZ Part-II, Opposite to GCPTTL, Dahej Gujrat • ADC attested commercial invoice confirming import of 1.125Kg Ticagrelor
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.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Velocity 60mg tablets vide Letter no. SM/DRA/DRAP/0119/490 dated 17-01-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
(Date of submission: 17-01-2019 vide diary no. 2086)

	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 Dascot Tablet 30mg (Daclatasvir), which was conducted on 26th January, 2018 and was presented in 278th meeting of Registration Board held on 29-31st January, 2017. Following two observations were reported in the report: i. The HPLC software is 21CFR Compliant. ii. Firm has shown all Audit trail reports. 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).	Firm has submitted following • Copy of form 6 dated 16-05-2017, confirming license to import of M/s Scotmann with M/s Glenmark Pharmaceuticals Ltd, Z/103/I, Dahej SEZ Part-II, Opposite to GCPTTL, Dahej Gujrat • ADC attested commercial invoice confirming import of 1.125Kg Ticagrelor
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice for 500mg Ticagrelor along with impurity standard A (50mg), B (7.5mg) and C (7.5mg)
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate (No. 1808965) dated 09-08-2018 issued by Food and Drugs control Administration Gujrat State India, valid upto 09-08-2018.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation form and vendor evaluation report
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API and reference standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development section.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols/SOPs for the development & testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches

11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch for long term stability studies: • Trial#01: 176 Tablets • Trial#02: 176 Tablets • Trial#03: 176 Tablets
	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 of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
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 submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms.
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that their formulation is as per innovator and provided various references for the formulation compatibility
18.	Record of comparative dissolution data.	• Firm has submitted data of comparative dissolution profile against reference product Brilinta tablets (Lot# KM0394) at pH 1.2, 4.5 and 6.8.and calculated values of f1 and f2 which were within accepted range
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for HPLC analysis for all the three batches.

Decision: Registration Board decided to approve registration of "Velocity tablets 60mg (Ticagrelor) by M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad". 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.#	**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)**
411.	M/s Ferozsons Labs, Amangarh, Nowshera.	Sitagen-M 100/1000 Tablets Each film coated tablet contains:- Sitagliptin phosphate monohydrate eq. to Sitagliptin (Immediate release) ……... 100mg Metformin HCl (sustained release) ……. 1000mg (Anti-diabetic)	Form-5 Dy. No: 3448 Dated. 25-01-2019 Rs.20,000/- dated 22-01-2019 As per DRAP policy	Approved by USFDA Last GMP inspection conducted on 10-01-2018recommending issuance of GMP certificate	
	STABILITY STUDY DATA SUBMITTED INITIALLY				

Drug	Sitagen-M 100/1000 Tablets		
Name of Manufacturer	M/s Ferozsons Labs, Amangarh, Nowshera.		
Manufacturer of API	Sitagliptin phosphate monohydrate: M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China. Metformin HCl: M/s Ipca Laboratories Limited – India.		
API Lot No.	Sitagliptin: M-20170112-D02-M06-01 Metformin HCl: 17127ML2ARM		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	SMXR-004	SMXR-005	SMXR-006
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	20-06-2018	20-06-2018	21-06-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

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.	**Sitagliptin:** • Copy of GMP Certificate issued on January 03, 2018 by Fuxin Food and Drug Administration People's Republic of China in the name of M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China, has been submitted. **Metformin:** • Copy of GMP Certificate issued on August 28, 2018 by Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State, India is submitted.
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.	Yes
Documents confirming import of API etc.	The firm has submitted • Photocopy of ADC (Peshawar) attested commercial invoice for 300kg Sitagliptin phosphate monohydrate invoice # HN170727-C dated: 12-08-2017, lot No. M-20170112-D02-M06-01 from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China • Photocopy of ADC (Peshawar) attested commercial invoice for 1000kg Metformin HCl invoice # MEG1718/1631990 dated: 12/02/2018 lot No. 17127ML2ARM from M/s Ipca Laboratories Limited – India.
All provided documents will be attested (name, sign and stamp) for	Yes

ensuring authenticity of data / documents.	
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
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.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Sitagen-M XR Tablets 100/1000 mg vide Letter no. PDFLL-657212091, dated 12-02-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: (Date of submission: 14-02-2019 vide diary no. 6562)

Name & Address of Manufacturer / Applicant

Sr. #	Question	Submission
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 "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS" by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted • Photocopy of ADC (Peshawar) attested commercial invoice for 300kg Sitagliptin phosphate monohydrate invoice # HN170727-C dated: 12-08-2017, lot No. M-20170112-D02-M06-01 from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China • Photocopy of ADC (Peshawar) attested commercial invoice for 1000kg Metformin HCl invoice # MEG1718/1631990 dated: 12/02/2018 lot No. 17127ML2ARM from M/s Ipca Laboratories Limited – India.
3.	Documents for the procurement of reference standard and impurity standards.	• Copy of NOC from DRAP Peshawar along with invoice for import of Sitagliptin Phosphate USP Reference Standard has been submitted. • Copy of P.O and invoice for import of Metformin HCl USP Reference Standard has been submitted. • No relevant document for procurement of impurity standards has been submitted.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sitagliptin:** • Copy of GMP Certificate issued on January 03, 2018 by Fuxin Food and Drug Administration People's Republic of China in the name of M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China, has been submitted. **Metformin:** • Copy of GMP Certificate issued on August 28, 2018 by Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State,

<table>
<tr><td></td><td></td><td>India is submitted.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted SOP “Procedure for induction of new vendor”</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Sitagliptin
Photocopy of COA of Batch No. M-20170112-D02-M06-01 issued from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China
• Metformin hydrochloride
Photocopy of COA of Batch No. 17127ML2ARM issued from M/s Ipca Laboratories Limited – India is submitted.
• Reference standards:
The firm has submitted the copy of COA’s of USP reference standard for Sitagliptin phosphate and Metformin HCl.</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 10 qualified persons</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 ‘Product Development Protocol of Sitagen-M XR Tablets (Sitagliptin + Metformin HCl)’.
Effective date 15-05-2018.</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
<table>
<tr><th colspan="4">SITAGEN-M XR Tablets 100mg/1000mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SMXR-004</td><td>1200 Tabs</td><td>20-06-2018</td><td>22-06-2018</td></tr>
<tr><td>SMXR-005</td><td>1200 Tabs</td><td>20-06-2018</td><td>23-06-2018</td></tr>
<tr><td>SMXR-006</td><td>1200 Tabs</td><td>21-06-2018</td><td>24-06-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sitagen-M XR Tablet 100mg/1000mg ; Stability Pack Size : 2 x 5’s)
• SMXR-004: Batch Size : 1200 Tablets
Yield 650 Tablets (65 Packs),
26 packs (Stability samples) For Accelerated (11 Packs) For Long Term (15 Packs)
39 packs (PD reference samples)
• SMXR-005: Batch Size : 1200 Tablets
Yield 630 Tablets (63 Packs)
26 packs (Stability samples For Accelerated (11 Packs) For Long Term (15 Packs)
37 packs (PD reference samples)
• SMXR-006: Batch Size : 1200 Tablets
Yield 660 Tablets (66 Packs).
26 packs (Stability samples For Accelerated (11 Packs) For Long Term (15 Packs)
40 packs (PD reference sample)</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</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period from 11-05-2018 to 11-01-2019.</td></tr>
</table>

	accelerated)	
13.	Method used for analysis of API along with COA.	Firm has provided the method used for analysis of API along with its certificate of analysis
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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months stability data (Accelerated & Real Time).
15.	Reports of stability studies of API from manufacturer.	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 Sitagliptin phosphate monohydrate from M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China And **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 Metformin HCl from M/s Ipca Laboratories Limited – India
16.	Analysis reports for excipients used.	The firm has submitted copy of Manufacturer's COAs and Firm analysis reports 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 (Janumet XR Tablets).
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile with the reference product Janumet XR Tablets manufactured by MSD International GmbH.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports

Feature	**Reference Product**	**Product of Ferozsons Laboratories Limited**
Brand name	Janumet XR Tablets 100mg/1000mg	Sitagen-M XR Tablets 100mg/1000mg
Batch No.	M045756	SMXR-004
Mfg. date	12-2016	06-2018

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)**
412.	M/s Ferozsons Labs, Amangarh, Nowshera.	Sitagen-M 50/1000 Tablets Each film coated tablet contains:- Sitagliptin phosphate monohydrate eq. to Sitagliptin (Immediate release) ……. 50mg Metformin HCl	Form-5 Dy. No: 125 Dated. 02-03-2015 Rs.20,000/- 14's,28's,30's As per SRO	Approved by USFDA Last GMP inspection conducted on 10-01-2018recommending issuance of GMP certificate	The applied formulation was previously approved in 276th meeting of Registration Board in the name of M/s Ferozsons as bilayer tablets. Now firm has requested to change

		(sustained release) ……. 1000mg (Anti-diabetic)			the formulation as per reference product and has submitted new Form 5 and relevant stability data. Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 0788903 dated 25-01-2019.

STABILITY STUDY DATA SUBMITTED INITIALLY			
Drug	Sitagen-M 50/1000 Tablets		
Name of Manufacturer	M/s Ferozsons Labs, Amangarh, Nowshera.		
Manufacturer of API	Sitagliptin phosphate monohydrate: M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China. Metformin HCl: M/s Ipca Laboratories Limited – India.		
API Lot No.	Sitagliptin: M-20170112-D02-M06-01 Metformin HCl: 17127ML2ARM		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	SMXR-001	SMXR-002	SMXR-003
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	21-04-2018	21-04-2018	21-04-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY	
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.	**Sitagliptin:** • Copy of GMP Certificate issued on January 03, 2018 by Fuxin Food and Drug Administration People's Republic of China in the name of M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China, has been submitted. **Metformin:** • Copy of GMP Certificate issued on August 28, 2018 by Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State, India is submitted.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported	Yes

by attested respective documents like chromatograms, laboratory reports, data sheets etc.	
Documents confirming import of API etc.	The firm has submitted • Photocopy of ADC (Peshawar) attested commercial invoice for 300kg Sitagliptin phosphate monohydrate invoice # HN170727-C dated: 12-08-2017, lot No. M-20170112-D02-M06-01 from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China • Photocopy of ADC (Peshawar) attested commercial invoice for 1000kg Metformin HCl invoice # MEG1718/1631990 dated: 12/02/2018 lot No. 17127ML2ARM from M/s Ipca Laboratories Limited – India.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
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.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Sitagen-M XR Tablets 50/1000 mg vide Letter no. PDFLL-658212091, dated 12-02-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting: (Date of submission: 14-02-2019 vide diary no. 6561)

Sr. #	Question	Submission
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 "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS" by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted • Photocopy of ADC (Peshawar) attested commercial invoice for 300kg Sitagliptin phosphate monohydrate invoice # HN170727-C dated: 12-08-2017, lot No. M-20170112-D02-M06-01 from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China • Photocopy of ADC (Peshawar) attested commercial invoice for 1000kg Metformin HCl invoice # MEG1718/1631990 dated: 12/02/2018 lot No. 17127ML2ARM from M/s Ipca Laboratories Limited – India.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• Copy of NOC from DRAP Peshawar along with invoice for import of Sitagliptin Phosphate USP Reference Standard has been submitted.
• Copy of P.O and invoice for import of Metformin HCl USP Reference Standard has been submitted.
• No relevant document for procurement of impurity standards has been submitted.</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:
• Copy of GMP Certificate issued on January 03, 2018 by Fuxin Food and Drug Administration People’s Republic of China in the name of M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China, has been submitted.
Metformin:
• Copy of GMP Certificate issued on August 28, 2018 by Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State, India is submitted.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted SOP “Procedure for induction of new vendor”</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Sitagliptin
Photocopy of COA of Batch No. M-20170112-D02-M06-01 issued from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China
• Metformin hydrochloride
Photocopy of COA of Batch No. 17127ML2ARM issued from M/s Ipca Laboratories Limited – India is submitted.
• Reference standards:
The firm has submitted the copy of COA’s of USP reference standard for Sitagliptin phosphate and Metformin HCl.</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 10 qualified persons</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 ‘Product Development Protocol of Sitagen-M XR Tablets (Sitagliptin + Metformin HCl)’ and Stability protocols.
Effective date 05-01-2018.</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
<table>
<tr><th colspan="4">SITAGEN-M XR Tablets 50mg/1000mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SMXR-001</td><td>1200 Tabs</td><td>21-04-2018</td><td>23-04-2018</td></tr>
<tr><td>SMXR-002</td><td>1200 Tabs</td><td>21-04-2018</td><td>24-04-2018</td></tr>
<tr><td>SMXR-003</td><td>1200 Tabs</td><td>21-04-2018</td><td>25-04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sitagen-M XR Tablet 50mg/1000mg ; Stability Pack Size : 2 x 5’s)
• SMXR-001: Batch Size : 1200 Tablets
Yield 630 Tablets (63 Packs),
26 packs (Stability samples) For Accelerated (11 Packs) For Long Term (15 Packs)
37 packs (PD reference samples)
• SMXR-002: Batch Size : 1200 Tablets</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Yield 620 Tablets (62 Packs)
26 packs (Stability samples For Accelerated (11 Packs) For Long Term (15 Packs)
36 packs (PD reference samples)
• SMXR-003: Batch Size : 1200 Tablets
Yield 640 Tablets (64 Packs).
26 packs (Stability samples For Accelerated (11 Packs) For Long Term (15 Packs)
38 packs (PD reference sample)</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period from 11-05-2018 to 11-01-2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of APIs along with their certificate of analysis.</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets 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 of Sitagliptin phosphate monohydrate from M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China
And
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 Metformin HCl from M/s Ipca Laboratories Limited – India</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of Manufacturer’s COAs and Firm analysis reports 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 (Janumet XR Tablets).</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Janumet XR Tablets manufactured by MSD International GmbH.
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Ferozsons Laboratories Limited</th></tr>
<tr><td>Brand name</td><td>Janumet XR Tablets 50mg/1000mg</td><td>Sitagen-M XR Tablets 50mg/1000mg</td></tr>
<tr><td>Batch No.</td><td>M040718</td><td>SMXR-001</td></tr>
<tr><td>Mfg. date</td><td>12-2016</td><td>04-2018</td></tr>
</table></td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports</td></tr>
<tr><td colspan="3">Evaluation by PEC:
• Dissolution method submitted by firm differs from that recommended by USFDA detailed as under:
<table>
<tr><td>Parameter</td><td>USFDA recommendation</td><td>Firm’s method</td></tr>
<tr><td>Time (Sitagliptin)</td><td>30 minutes</td><td>45 minutes</td></tr>
<tr><td>Apparatus</td><td>Paddle</td><td>Basket</td></tr>
<tr><td>RPM</td><td>75</td><td>100</td></tr>
</table></td></tr>
</table>

- In contrary to reference product wherein extended release metformin core has been prepared by incorporating matrix forming polymer in the metformin core, whereas firm has applied an extended release coating over the metformin core. Clarification/justification shall be submitted for this variation.
- **Upon communication of above observations vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-II) dated 04-04-2019, firm has responded as under:**
- Firm has submitted analytical record for performance of dissolution data as per USFDA recommendations for all the three stability batches of both strengths, wherein the results of Sitagliptin are more than 90% in 30 minutes. Moreover firm has committed that in future we will follow USFDA recommendations for testing the dissolution of our products placed on real time stability.
- Firm has referred to literature of various formulations of Metformin Extended release tablets approved by USFDA, wherein an extended release coating over the metformin core has been applied and this technology has been named as "osmotic pump technology system".

Decision: Registration Board was apprised of the decision of 151st meeting of Appellate Board regarding Sovel 400/100mg Tablet (Sofosbuvir/Velpatasvir) of M/s Indus Pharmaceuticals, Karachi, wherein Board agreed with the submission made by the firm and allowed the appeal regarding GMP status of their supplier of Sofosbuvir i.e. M/s Bejing Huikang Boyuan Chemical Co., Ltd. Subsequently Registation Board in its 288th meeting approved the said product of M/s Indus Pharmaceuticals, Karachi.
Hence considering the baove cited reference and submitted stability studies data decided to approve Sitagen-M 100/1000 Tablets of M/s Ferozsons Labs, Amangarh, Nowshera. 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.
The Board also approved the change of formulation of Sitagen –M 50/1000 tablets as per reference product.

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)
413.	M/s Hilton Pharma (Pvt.) Ltd. Karachi	Hilfo-B 25 mg Tablet Each film coated tablet contains: Tenofovir Alafenamide fumarate equivalent to 25 mg Tenofovir Alafenamide (Anti-viral)	Form 5-D Diary No. 3666 dated 23-12-2016 Rs.50,000/- dated 23-12-2016 30's As per DPC	Approved by USFDA Not applicable. GMP Certificate issued on 19-02-2018.	

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Hilfo-B 25 mg Tablet		
Name of Manufacturer	M/s Hilton Pharma (Pvt.) Ltd. Karachi		
Manufacturer of API	M/s YiChang HEC ChangJiang Pharmaceutical Co., Ltd, Hubei Province, China		
API Lot No.	HCS171610-01		
Description of Pack (Container closure system)	Alu-Alu blister foil with unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months	Real Time: 6 Months	
Frequency	Real Time: 0,3 & 6 (months)	Accelerated: 0,3 & 6 (months)	
Batch No.	HFB-281307-4	HFB-281307-5	HFB-281307-6
Batch Size	4,500 Tablets	4,500 Tablets	4,500 Tablets

Manufacturing Date	09-08-2018	09-08-2018	09-08-2018
Date of Initiation	11-09-2018	11-09-2018	11-09-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

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.	The firm has provided copy of Certificate of GMP compliance issued to M/s Jiangxi Synergy Pharmaceutical Co., Ltd. by Germany valid Up to 27-11-2018
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.	Yes
Documents confirming import of API etc.	Commercial Invoices signed & stamped by ADC DRAP, Karachi dated 28-03-2017 has been attached.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
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.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Hilfo-B 25mg tablets vide Letter no. AQS/SK/191104-01, dated 11-04-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
(Date of submission: 15-04-2019 vide diary no. 3605)

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 "HILVEL 400mg + 100mg (Sofosbuvir + Velpatasvir)", which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017. Registration Board decided to approve registration of "HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir" by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Following two observations were reported in the report: i. The HPLC software is 21 CFR compliant. ii. Audit trail on the testing reports of Hilvel Tablets

<table>
<tr><td></td><td></td><td>400mg+100mg is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Form 6 signed & stamped by ADC DRAP, Karachi dated 03-01-2018 for the import of Tenofovir Alfenamide Fumarate has been submitted.
<table>
<tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th></tr>
<tr><td>Not mentioned on invoice</td><td>WIS1700069</td><td>300gm</td></tr>
</table></td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted a letter from M/s Yichang HEC Changjiang Pharmaceutical Co., Ltd., China declaring the submission of working standard & impurity standards (A, PMPA) for Tenofovir Alfenamide Fumarate by hand through M/s Wis International Pvt. Ltd to M/s Hilton Pharma (Pvt.) Ltd.</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 provided copy of Manufacturing License for Pharmaceutical (Certificate # 20160013) issued to M/s YiChang HEC ChangJiang Pharmaceutical Co., Ltd, Hubei Province, China by Hubeii Food & Drug Administration valid Up to 31-12-2020.
• The GMP certificate mentioning the name of API i.e., Tenofovir Alfenamide, has been issued by Yichang Food and Drug Administration, which is not the relevant regulatory authority.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted photocopy of “SOP for Selection of manufacturer for API/Excipient and Procurement Procedure”, SOP No: PDV-FM-068 with effective date 02-03-2018.
Version no: 01
• Copy of “Vendor’s Audit form” filled for M/s YiChang HEC ChangJiang Pharmaceutical Co., Ltd, Hubei Province, China, dated 20-03-2019</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• The firm has submitted certificate of analysis for API (Batch# HCS171610-01), working standard and impurity standard for Tenofovir Alfenamide Fumarate.
• The Qualification report of reference standards & Impurity standards have been submitted form HEC R&D center.</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 Purchase Order/Invoices for the 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>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 18 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 Development Protocol for Lab scale batch manufacturing of Hilfo-B 25mg Film coated tablets.
• Project code # HPL/07/18/HFB
• Issued on July, 2018
• The SOP mentions the details of master formulation & manufacturing method for both products. Copies of stability protocols have also been submitted for both products.</td></tr>
</table>

<table>
<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 Hilfo-B 25mg tablets, such as.
<table>
<tr><th colspan="3">Hilfo-B 25mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>HFB-281307-4</td><td>09-08-2018</td><td>4,500 Tablets</td></tr>
<tr><td>HFB-281307-5</td><td>09-08-2018</td><td>4,500 Tablets</td></tr>
<tr><td>HFB-281307-6</td><td>09-08-2018</td><td>4,500 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">Hilfo-B 25mg Tablet</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>MRG-266201-10</td><td>130 Tablets</td></tr>
<tr><td>MRG-266301-11</td><td>130 Tablets</td></tr>
<tr><td>MRG-266401-12</td><td>130 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>The firm has submitted photocopies of digital printouts of 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 and report for Hilfo-B (batch #.HCS171610-01)
• Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs have been submitted.</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 PD-FPS/136/00) for Hilfo-B 25 mg tablets 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 Tenofovir Alfenamide fumarate from API manufacturer for both Accelerated (25°C ± 2°C / 60% ± 5%RH)& Long term (5°C ± 3°C) conditions.</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 Hilfo-B tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator’s product tablet and also stability studies have not shown any incompatibility or significant degradation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted F2 factor protocol & reports. The details of reference product & Sample product are as follows:
<table>
<tr><th colspan="3">Hilfo-B 25mg Tablet</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Tenofomide 25mg tablet</td><td>Hilfo-B 25mg tablet</td></tr>
<tr><td>Batch No.</td><td>001FB1</td><td>HFB-281407-5</td></tr>
<tr><td>Expiry date</td><td>01-2021</td><td>--</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
i. pH 1.2 HCl buffer
ii. pH 4.5 Acetate buffer
iii. pH 6.8 Phosphate buffer
• As per submitted reports both reference and trial product</td></tr>
</table>

		released more than 85% at all three dissolution mediums. • Firm has submitted UV spectrums and raw data sheets for the CDP study.
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

Remarks of Evaluator:

- Firm has also submitted report from FID, Karachi for verification of storage facility concluding as under:

"The above facility based on its suitability is recommended for the storage of all types of bio-tech vaccines required to be stored at 2-8^{o}C.

- Firm has also submitted a declaration from M/s YiChang HEC ChangJiang Pharmaceutical Co., Ltd, Hubei Province, China stating that the company name, Yichang Dongyang Chingjiang Pharm Co., Ltd on Chinese cFDA website is the exactly same company with us. The translation issue causes the difference that Dongyang is our Chinese name pronunciation.

Decision: Registration Board decided to approve registration of "Hilfo-B 25 mg Tablet (Tenofovir Alafenamide fumarate equivalent to 25 mg) by M/s Hilton Pharma (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#	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
414.	M/s Scilife Pharma (Pvt.) Ltd, Plot FD-57/58-A2 Korangi Creek Industrial Park , Karachi -	Teno-Alf Tablet Each film coated tablet contains: Tenofovir alafenamide fumarate eq to Tenofovir alafenamide……25mg Anti-Viral (In house specification)	Form 5-D Dy. No. 1129 02-5-2017 PKR 50,000/- (02-5-2017) 10's, 30's Alu-Alu Blister As per SRO	Vemlidy Tablets by Gilead Sciences (**USFDA** Approved) GMP inspection report dated: 10-07-2018 concluding acceptable level of compliance.

Remarks of Evaluator:

The firm has submitted stability study data along with required documents as per checklist approved in 276th meeting of Registration Board for exemption from "On site investigation of submitted stability data". Details of submitted data are as under:

(Dy.# 34588 dated 18-10-2018)

STABILITY STUDY DATA

Drug	Teno- Alf Tablet 25mg		
Name of Manufacturer	M/s Scilife Pharma (Pvt.) Ltd, Plot FD-57/58-A2 Korangi Creek Industrial Park , Karachi		
Manufacturer of API	M/s Shanghai Desano Chemical Pharmaceutical Co., China		
API Lot No.	DBH2581-B15A-170904		
Description of Pack (Container closure system)	Alu Alu blister with Unit Carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 0,3,6 months		Accelerated: 0,3,6 months
Frequency	Accelerated: 0,3,6,9,12,18,24,36 months		Real Time: 0,3,6 months
Batch No.	006B18	007B18	008B18
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets

Manufacturing Date	04-01-2018	04-01-2018	04-01-2018
Date of Initiation	02-02-2018	02-02-2018	02-02-2018
No. of Batches	3		
Date of Submission	Dy.# 34588 dated 18-10-2018		

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.	Copy of GMP certificate Certificate No. : SH20170006 Certifying Authority: China Food and Drug Administration. Validity: 08-02-2022 The mentioned bulk drug on GMP certificate is Efavirenz whereas, you have applied for Tenofovir Alafenamide.
3.	Protocols followed for conduction of stability study and details of tests.	Yes Stability Study Protocol Number: P-FSB-105/00.
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Registration Board in its 276th Meeting decided that following time points for stability studies shall be adopted: Accelerated stability studies: 0, 1st , 2nd , 3rd , 4th& 6th months whereas, you have conducted accelerated Stability at following time points Accelerated stability studies: 0,3rd& 6th months.
5.	Documents confirming import of API etc.	i. Copy of Form 6 (License to import drug for Clinical Trial/Examination, Test or Analysis). Supplier: M/s Shanghai Desano Chemical Pharmaceutical Co., China Quantity: 400g ii. Copy of Commercial Invoice ADC Attestation Date: 08-11-2017 Invoice No. : DL-Y-2017-0297 Batch No.: DBH2581-B15A-170904 Mfg Date: 18, Sep 2017 Exp. Date: 17, March 2019 Quantity: 400g (Including working standard)
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

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 ROMILAST (Roflumilast 500mcg) Tablets and TASVIR (Daclatasvir 60mg) Tablets in its 275th Meeting. • Date of Inspection: 05th October, 2017 (Morning). • The HPLC software is 21CFR Compliant as per record of the firm. • Audit trail on the testing reports (of ROMILAST and TASVIR) can be made. Physically the related audit trial was checked and found in order.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	iii. Copy of Form 6 (License to import drug for Clinical Trial/Examination, Test or Analysis).

<table>
<tr><td></td><td></td><td>Supplier: M/s Shanghai Desano Chemical Pharmaceutical Co., China
Quantity: 400g
iv. Copy of Commercial Invoice
ADC Attestation Date: 08-11-2017
Invoice No. : DL-Y-2017-0297
Batch No.: DBH2581-B15A-170904
Mfg Date: 18, Sep 2017
Exp. Date: 17, March 2019
Quantity: 400g
(Including working standard)
The storage condition of API as per Manufacturer requirement is 2-8°C.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><table><tr><th>Material</th><th>Batch No.</th><th>Qty.</th></tr><tr><td>Tenofovir Alafenamide Fumarate Working Standard</td><td>251A1601</td><td>100 mg</td></tr><tr><td>Fumaric Acid Working Standard</td><td>BCBP2928V</td><td>50mg</td></tr><tr><td>Isomer 6, Isomer 7</td><td>161011-1-1</td><td>20mg</td></tr></table></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><u>Copy of GMP certificate</u>
Certificate No. : SH20170006
Certifying Authority: China Food and Drug Administration.
Validity: 08-02-2022
The mentioned bulk drug on GMP certificate is Efavirenz whereas, you have applied for Tenofovir Alafenamide.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Not provided.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Firm has submitted certificate of analysis of working standard and the impurity standards.<table><tr><td>Material</td><td>Batch No.</td></tr><tr><td>Tenofovir Alafenamide Fumarate Working Standard</td><td>251A1601</td></tr><tr><td>Fumaric Acid Working Standard</td><td>BCBP2928V</td></tr><tr><td>Isomer 6, Isomer 7</td><td>161011-1-1</td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td><table><tr><th>Excipient</th><th>Source</th><th>Batch No.</th></tr><tr><td>MCC 102</td><td>Sigachi Industries, Pashammailaram, India</td><td>SH/17070968</td></tr><tr><td>Lactose Monohydrate</td><td>Kerry Ingredients, Mumbai , India</td><td>0001434878</td></tr><tr><td>Croscarmellose</td><td>Gujarat Microwax Nandasan, India</td><td>7111507225</td></tr><tr><td>Magnesium Stearate</td><td>Nitika Pharmaceutical Specialities, Nagpur</td><td>MGST1F252</td></tr><tr><td>HPMC</td><td>Shin Etsu</td><td>DEAT291993</td></tr><tr><td>PEG 6000</td><td>Pan Asia Chemical Corp</td><td>20150320</td></tr><tr><td>Titanium Dioxide</td><td>Cosmo Chemical Korea</td><td>K521-10120</td></tr><tr><td>Talcum Powder</td><td>Nitika Pharmaceutical Specialities, Nagpur</td><td>PUTA2F163</td></tr><tr><td>Yellow Ferric Oxide</td><td>Bush Boake Allen Pakistan Pvt. Limited</td><td>1280194001</td></tr></table></td></tr>
</table>

<table>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>
<table>
<tr><th>Name</th><th>Designation</th><th>Qualification</th><th>Experience</th></tr>
<tr><td>Jawad ahmed</td><td>Sr. Manager R&D</td><td>B-Pharmacy</td><td>15 years</td></tr>
<tr><td>Syed M. Atif Abbas</td><td>Ast. Manager R&D</td><td>d-Pharmacy</td><td>07 years</td></tr>
<tr><td>Adnan Ahmed</td><td>Asst. Manager R&D</td><td>M.Sc analytical Chemistry</td><td>07 years</td></tr>
<tr><td>Ghulam Rasool</td><td>Sr. Executive R&D</td><td>BS Organic Chemistry</td><td>04 years</td></tr>
<tr><td>Ishaq Ahemd</td><td>Executive R&D</td><td>BS Analytical Chemistry</td><td>03 years</td></tr>
<tr><td>Danish Khalid</td><td>Officer R&D</td><td>M.Sc Organic Chemistry</td><td>01 years</td></tr>
<tr><td>Ashraf Hussain</td><td>Sr. R&D Operatro</td><td>Intermediate</td><td>13 years</td></tr>
</table>
</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 provided authorized protocols for product development and stability testing of trial batches.
Stability Study Protocol Number: P-FSB-105/00.</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided complete batch manufacturing record and batch packaging record of all the three batches.</td></tr>
<tr><td>11</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
<table>
<tr><th>Description</th><th>006B18</th><th>007B18</th><th>008B18</th></tr>
<tr><td>Theoretical Batch Size</td><td>2500</td><td>2500</td><td>2500</td></tr>
<tr><td>Total produced</td><td>2297</td><td>2295</td><td>2302</td></tr>
<tr><td>Used for initial testing</td><td>50</td><td>50</td><td>50</td></tr>
<tr><td>Kept on 30°C/RH75%</td><td>350</td><td>350</td><td>350</td></tr>
<tr><td>Kept on 40°C/RH75%</td><td>100</td><td>100</td><td>100</td></tr>
<tr><td>Remaining on 30° C/RH75%</td><td>270</td><td>270</td><td>270</td></tr>
<tr><td>Remaining on 40° C/RH75%</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Total used for CDP</td><td>50</td><td>-</td><td>-</td></tr>
<tr><td>Remaining quantities in R&D</td><td>1747</td><td>1795</td><td>1802</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>Tabular record of Digital data logger for temperature and humidity monitoring of stability chambers has been submitted.</td></tr>
<tr><td>13</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis but has not performed related substances, test for enantiomer, residual solvent.</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets.</td></tr>
</table>

15	Reports of stability studies of API from manufacturer.	Firm has submitted stability data of 3 batches of API conducted at 2-8°C for long term but upto 24 months and 25°C for accelerated studies till 6 months. Accelerated Term | 25°C±2&60%±5 % | 0,1,2,3,6 month Long Term | 5°C±3 | 0,3,6,9,12,18 & 24 month
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.	Firm has not performed drug excipient compatibility studies as they claim their qualitative composition of innovator and Teno-Alf is same. However, that is not the case. The comparison of innovator product and Teno-Alf is mentioned below: **Vemlidy Innovator**: Croscarmellose sodium, Microcrystalline cellulose, Magnesium stearate, Lactose Monohydrate, **Film Coat**, **Polyvinyl alcohol**, PEG, Talc, Titanium Dioxide, Yellow Ferric Oxide **Teno-Alf**: Croscarmellose sodium, Microcrystalline cellulose, Magnesium stearate, Lactose Monohydrate, **Film Coat**, HPMC, PEG, Talc, Titanium Dioxide, Yellow Ferric Oxide
18	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile with the reference product Vemlidy 25mg tablet at pH 1.2, pH 4.5 and pH 6.8.
19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	

Evaluation by PEC:
Firm has submitted SOP for cleaning and usage of Refrigerator and freezer as evidence for requisite facility for storage of API.

Decision: Registration Board decided to approve registration of "Teno-Alf Tablet (Tenofovir Alafenamide fumarate equivalent to 25 mg) by M/s Scilife Pharma (Pvt.) Ltd, Plot FD-57/58-A2Korangi Creek Industrial Park , 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 GMP Inspection Report Date & Remarks
415.	M/s Scilife Pharma (Pvt.) Ltd Plot FD-57/58-A2 Korangi Creek Industrial Park Karachi	Sofolos Tablet Each film coated tablet contains:- Sofosbuvir……400mg Ledipasvir……90mg (Direct-acting antiviral agent against the hepatitis C virus) (MFG Specs)	Form 5-D Dairy No. 1271 dated 21-09-2016 Rs.50,000/- As per PRC	Harvoni, FDA. Harvoni, Ferozsons, Pakistan. GMP inspection report dated 10-07-2018 concluding acceptable level of compliance.

STABILITY STUDY DATA			
Drug	Soladi Film Coated Tablet Other proposed brand names Sofo-Led Hepled Ledisof Scihop-L Sciled-C		
Name of Manufacturer	M/s Scilife Pharma (Pvt.) Ltd, Plot FD-57/58-A2 Korangi Creek Industrial Park , Karachi		
Manufacturer of API	Sofosbuvir: M/s Nantong Chanyoo Pharmatech. Co. ltd.		
	Ledipasvir –Co-povidone: Ruyuan HEC Pharm		
API Lot No.	Sofosbuvir: RD-SFB (Form VI) -201703091		
	Ledipasvir –Co-povidone: YAXi-201704003		
Description of Pack (Container closure system)	Alu- Alu blister with unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH 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.	SF002	SF003	SF004
Batch Size	800 tablets	800 tablets	800 tablets
Manufacturing Date	06-2017	06-2017	06-2017
Date of Initiation	07-2017	07-2017	07-2017
No. of Batches	3		
Date of Submission	26-11-2018 (Dy. No. 38654)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes Sofosbuvir: RD-SFB (Form VI) -201703091 Ledipasvir –Co-povidone: YAXi-201701002(Previous Lot No) Ledipasvir –Co-povidone: YAXi-201704003(New Lot No)
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 Certificate of GMP compliance issued to M/s Nantong Chanyoo Pharmatech by Agency for medicinal products and medical devices of the Republic of Solvenia. (verified from EU GMP database).
		Ledipasvir –Co-povidone: Copy of GMP certificate issued by Shaoguan food and Drug Administration has been submitted for M/s Ruyuan HEC Pharm Co., Ltd. The certificate is valid up to 17-06-2018.
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	Yes

	chromatograms, laboratory reports, data sheets etc.	
5.	Documents confirming import of API etc.	**Sofosbuvir** • Copy of Form 6 (License to Import drug) issued by ADC (Karachi) dated 15-06-2017, for the import of Sofosbuvir 1 kg from the M/s Nantong Chanyoo Pharmatech Co., Ltd. China has been submitted. • Copy of Commercial Invoice (invoice no. CY117186B) attested by ADC (Karachi) dated 20-06-2017 has been submitted. Batch No RD-SFB (Form VI) -201703091. • Issuer: Changzhou Pharmaceutical Factory.
		Ledipasvir Co-povidone Correction in Ledipasvir Copovidone Lot No. used in stability batches of Sofoled, erroneously the ADC approval of Ledipasvir Copovidone attached is not of that lot which is used in submitted stability batches. The batches were manufactured by another lot which was received from manufacturer via FedEx to Scilife Pharma Private without any custom clearance.
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

- Brand name mentioned on Form 5 is Soladi whereas in protocols and provided data you have mentioned Sofo-Led.
- Scilife already have the export purpose registration of the said combination Soladi with Brand name Sofo-Led 400/90 mg Tablet. Hence the overall technical and stability documents of the said combination was being prepared, done and submitted with the brand name Sofo-Led tablet.

REQUEST OF EXEMPTION ROM 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 approved ROMILAST (Roflumilast 500mcg) Tablets and TASVIR (Daclatasvir 60mg) Tablets in its 275th Meeting. • Date of Inspection: 05th October, 2017 (Morning). • The HPLC software is 21CFR Compliant as per record of the firm. • Audit trail on the testing reports (of ROMILAST and TASVIR) can be made. Physically the related audit trial was checked and found in order.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**<u>Sofosbuvir</u>** **i.** Copy of Form 5 (License to Import drug) issued by Licensing Authority (Karachi) dated 15-06-2017, for the import of Sofosbuvir from the M/s Nantong Chanyoo Pharmatech Co., Ltd. China has been submitted.

<table>
<tr><td></td><td></td><td>ii. Copy of Commercial Invoice
Invoice no. CY117186B
Attested by ADC (Karachi) dated 20-06-2017.
Batch No RD-SFB (Form VI) -201703091.
Quantity: 1 Kg
Issuer: Changzhou Pharmaceutical Factory.</td></tr>
<tr><td></td><td></td><td><u>Ledipasvir Co-povidone (0.5 Kg)</u>
Correction in Ledipasvir Copovidone Lot No. used in stability batches of Sofoled, erroneously the ADC approval of Ledipasvir Copovidone attached is not of that lot which is used in submitted stability batches. The batches were manufactured by another lot which was received from manufacturer via FedEx to Scilife Pharma Private without any custom clearance. As a proof of shipment procured from the approved source firm has submitted the following documents:
Shipment and Transportation Documents
• Airway Bill
• Good Declaration From Fed- Ex
• Parcel Travel History
• Fed- Ex proof of delivery
• Import Duty Statement</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><u>Sofosbuvir</u>
Changzhou Pharmaceutical Factory have provided material of Sofosbuvir Form VI 1.5Kg to M/s Scilife Pharma, along with dispatched impurities of Sofosbuvir Form VI along with working standard against bracketed invoice no CyI16166</td></tr>
<tr><td></td><td></td><td><u>Ledipasvir-Co-povidone DMF Declaration</u>
Ruyuan Pharma HEC Pharm Co. confirmed that they have supplied Ledipasvir&Co-povidone Solid dispersion along with working standard and impurities standard in Feb 2017.</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>Sofosbuvir: Copy of Certificate of GMP compliance issued to M/s Nantong Chanyoo Pharmatech by Agency for medicinal products and medical devices of the Republic of Solvenia. (verified from EU GMP database)
Ledipasvir –Co-povidone: Copy of GMP certificate issued by Shaoguan food and Drug Administration has been submitted for M/s Ruyuan HEC Pharm Co., Ltd. The certificate is valid up to 12-12-2018.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for qualification of vendors for raw materials and packaging material.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td><u>Sofosbuvir</u>
<table>
<tr><th>API</th><th>Batch. #</th></tr>
<tr><td>Sofosbuvir Form VI</td><td>RD-SFB-201703091</td></tr>
<tr><td>Sofosbuvir Form VI</td><td>WSFB39-170401</td></tr>
<tr><td>SFBA-1</td><td>WSFB10-170601</td></tr>
<tr><td>Impurity A SFB</td><td>WSFB13-170601</td></tr>
<tr><td>Impurity B SFB</td><td>WSFB14-170601</td></tr>
<tr><td>Methyl-ester SFB</td><td>WSFB07-170601</td></tr>
<tr><td>Amino-SFB</td><td>WSFB08-170601</td></tr>
<tr><td>Chloro-SFB</td><td>WSFB05-170601</td></tr>
<tr><td>Pentafluorophenol</td><td>WSFB12-170601</td></tr>
<tr><td>2-hydroxymethyl SFB</td><td>WSFB09-170601</td></tr>
<tr><td>SFBMA</td><td>WSFB11-170601</td></tr>
<tr><td>SFBD3</td><td>WSFB15-170601</td></tr>
</table></td></tr>
</table>

		SFBE: WSFB02-170601 SFBD1: WSFB03-170601 SFBD2: WSFB02-170601
		Ledipasvir and Co-povidone Solid Dispersion **API**: **YAXi-201701002 (Previous Lot No COA)** Reference Standard Supplied By Dongguan Changan HEC Pharm: HCS15429-42 **Scilife COA Working Standard Manufacturer** HEC Pharma **Supplier** WIS Group: WS-RD-LED/01 **Impurity A Reference Standard** Supplied By Dongguan Changan HEC Pharm: HCS14416-25-02 **Impurity C Reference Standard** Supplied By Dongguan Changan HEC Pharm: HCS14401-22-02
7.	Documents for the procurement of excipients used in product development?	The firm has submitted commercial invoices & COAs of excipients used in formulation from relevant manufacturers. **Excipient** / **Source** / **Batch No.** MCC 102 / Sigachi Industries, Pashammailaram, India / SH/16101727 Lactose Monohydrate / Kerry Ingredients, Mumbai , India / 0000981612 Croscarmellose / Gujarat Microwax Nandasan, India / 7111507225 Colloidal Silicon Dioxide Aerosil / Evonik Industries Germany / 156050314 Magnesium Stearate / Nitika Pharmaceutical Specialities, Nagpur / MGST1F252 HPMC / Shin Etsu / DEAT261725 PEG 6000 / Pan Asia Chemical Corp / 20150320 **Titanium Dioxide** / **Cosmo Chemical Korea** / **K521-10120** Talcum Powder / Nitika Pharmaceutical Specialities, Nagpur / PUTA2F163
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted photocopy of List of qualified staff along with their training record involved in product development.
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted SOP of Product development and protocol for stability studies specific to the product.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted photocopy of Batch Manufacturing Record and batch packaging record of the following 03 Batches.

<table>
<tr><td></td><td></td><td><u>Batch Reconciliation After Batch Completion</u>
SF002
324 Tablets:
SF003
322 Tablets:
SF003
322 Tablets:</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Description</th><th>B.No:SF002</th><th>B.No:SF003</th><th>B.No:SF004</th></tr>
<tr><td>Theoretical Batch Size</td><td>800 tablets</td><td>800 tablets</td><td>800 tablets</td></tr>
<tr><td>Total produced</td><td>761</td><td>762</td><td>762</td></tr>
<tr><td>Used for initial testing</td><td>50</td><td>50</td><td>50</td></tr>
<tr><td>Kept On 30°C/RH75%</td><td>245</td><td>245</td><td>245</td></tr>
<tr><td>Kept On 40°C/RH75%</td><td>70</td><td>70</td><td>70</td></tr>
<tr><td>Remaining On 30° C/RH75%</td><td>105</td><td>105</td><td>105</td></tr>
<tr><td>Remaining On 40° C/RH75%</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Total used for CDP</td><td>72</td><td>-</td><td>-</td></tr>
<tr><td>Remaining quantities in R&D</td><td>324</td><td>397</td><td>397</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>• Tabular record of Digital data logger for temperature and humidity monitoring of stability chambers has been submitted.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Sofosbuvir & Ledipasvir Co-povidone
Firm has provided method but not performed the complete testing of API e.g. Isomers identification, Related substances and residual solvent Their provided method is as per vendor.</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 specification & Test method.
• 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>Sofosbuvir
The firm has submitted copies of reports of 06 Months Accelerated and 12 Months Real Time Stability Study Data of 03 Batches of API as per Zone-IVa conditions
Ledipasvir and Copovidone
The firm has submitted copies of reports of 12 Months Accelerated and 12 Months Real Time Stability Study ($30^{o}C \pm 2\ ^{o}C$, $60 \pm 5\%$) 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.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Firm has not performed drug excipient compatibility studies as they claim their qualitative composition of innovator and Sofo-Led is same. However, that is not the case. The comparison of innovator product and Sofo-Led is mentioned below:
<table>
<tr><th>Harvoni Innovator</th><th>Sofo-Led</th></tr>
<tr><td>Copovidone
Croscarmellose sodium</td><td>
Croscarmellose sodium</td></tr>
</table>
</td></tr>
</table>

		Microcrystalline cellulose / Microcrystalline cellulose Magnesium stearate / Magnesium stearate Lactose Monohydrate / Lactose Monohydrate Colloidal Silicon Dioxide / Colloidal Silicon Dioxide **Film Coat** / **Film Coat** **Polyvinyl alcohol** / HPMC PEG / PEG Talc / Talc Titanium Dioxide / Titanium Dioxide **FDC Yellow Subset Yellow, FCF Aluminum Lake**
18.	Record of comparative dissolution data.	Firm has submitted protocol for comparative dissolution at pH 1.2, pH 4.5 and pH 6.8. The details of reference product & Sample product are as follows: Feature: Reference product by Hetero Labs Ltd: Product of M/s Scilife Brand name: Ledifos 400/90mg: Sofo-Led 400/90mg Batch No.: 3117251: SF002 Mfg. date: 01-2017: 06-2017
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.
Decision: Registration Board decided to approve registration of "Sofolos Tablet400/90 (Sofosbuvir/Ledipasvir) by M/s Scilife Pharma (Pvt.) Ltd, Plot FD-57/58-A2Korangi Creek Industrial Park , 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.		

Case No. 07 Miscellaneous Cases.

a. Cases Referred by Appellate Board:

1. 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:

416.	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 (Lyophilized Powder For Solution For Intravenous Injection)
	Composition	Each vial contains: 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. • 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.	
417.	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 (Lyophilized Powder For Solution For Intravenous Injection)
	Composition	Each vial contains: 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. • 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 i. Nomenclature ii. Structure iii. General properties
		3.2.S.2	**Manufacture**	Detail submitted for i. Manufacturer(s) ii. Description of Manufacturing Process and Process Controls
		3.2.S.3	**Characterization**	Detail submitted for i. Elucidation of Structure and other Characteristics ii. Impurities
		3.2.S.4	**Control of Drug Substance**	Detail submitted for i. Control of Drug Substance ii. Specification iii. Analytical Procedures iv. Validation of Analytical Procedures

				v. Batch Analyses 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 i. Manufacturer(s) ii. Batch Formula iii. Description of Manufacturing Process and Process Controls iv. Controls of Critical Steps and Intermediates Undertaking has been submitted for Process validation
		3.2.P.4	**Control of Excipient**	Detail submitted for i. Specifications ii. Analytical Procedures All excipients used are of Pharmacopoeal grades
		3.2.P.5	**Control of Drug Product**	Detail submitted for i. Specification(s) ii. Analytical Procedures 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: i. Stability Summary and Conclusions ii. Post-approval Stability Protocol and Stability Commitment 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:-3
  "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 & 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.

Decision:

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 of 288th meeting: 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.

Evaluation by PEC: The firm has submitted that our applications of "Omera (Omeprazole) 40mg injection" & "Esomega (Esomeprazole) 40 mg injection" were also submitted on Form-5 dated 04-10-2017 & 03-10-2017 respectively. Hence the firm as requested to consider their products on Form-5 where the stability data and process validation is not required for registration.

Decision: **Registration Board acceded with firm's request and approved "Omera (Omeprazole) 40mg injection" & "Esomega (Esomeprazole) 40 mg injection". 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.

b. Registration of Cysteamine

Chief Drugs Controller, Punjab vide letter No. CDC/INT-CC/172/2019 dated 08-01-2019 has requested the CEO, DRAP to take the needful action to ensure the availability of Cysteamine in Pakistan by registering it at earliest, since the said drug is not registered in Pakistan and it is indicated for life threatning genetic disorder named Cystinosis.

In this regard it is submitted for information of Board that till date no registration application of "Cysteamine" could be identified in available entered record.

Decision: **Registration Board decided that any submitted application of "Cysteamine" will be considered on priority upon completion of relevant codal formalities.**

Case no. 01: Registration applications for local manufacturing of (Human) drugs

a. Deferred cases

418.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Tamflo Capsule
	Composition	Each capsule contains: Tamsulosin hydrochloride…..0.4mg
	Diary No. Date of R& I & fee	Dy No. 1174: 15-10-2014 PKR 20,000/-: 02-10-2014
	Pharmacological Group	Selective alpha 1 receptor antagonist
	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.	Diffundox XL 400 microgram Capsules by Winthrop Pharmaceuticals (MHRA Approved)
	Me-too status	Tamsolin capsule by Getz
	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[3]	Source of pellets along with GMP of manufacturer, stability study data of pellets is not submitted.
	Decision of previous meeting of Registration Board	Registration Board deferred the case for further deliberation**(M-284)**
	Evaluation by PEC	Firm has submitted source of pellets from Vision Pharmaceuticals, Islamabad along with stability data of 3 batches. After the use of pellets, the label claim will become Each capsule contains: Tamsulosin hydrochloride (as SR pellets)……..0.4mg
	Decision: Approved.	
419.	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: 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 (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: Each 5ml of solution Contains:

		Sulbutamol as Sulphate…2mg
	Decision of 288th meeting of Registration Board	Deferred for submission of fee for revision of dosage form.
	Evaluation by PEC	Firm has submitted the balance fee i.e. 15,000/- dated 09-05-2019 for revision of dosage form
	Decision: Approved.	
420.	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: Zinc as Sulphate Monohydrate…20mg
	Diary No. Date of R& I & fee	Dy. No 39943: 04-12-2018 PKR 20,000/- : 04-12-2018
	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: Each 5ml of solution Contains: Zinc as Sulphate Monohydrate…20mg
	Decision of 288th meeting of Registration Board	Deferred for submission of fee for revision of dosage form.
	Evaluation by PEC	Firm has submitted the balance fee i.e. 15,000/- dated 09-05-2019 for revision of dosage form
	Decision: Approved.	

Case No. 02: Registration Applications of Newly Granted DML or New Section (Human)

a. New DML

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.

Some applications have already been considered by the Board in its 288th meeting. The details of freshly applied products along with balance of molecules left after 288th meeting is given in the table below.

Following applications applied by firm are hereby presented for consideration of Board.

Sr. No	Section	No. of molecules considered in M-288	Fresh molecules applied	Fresh products applied	Total molecules
1.	Sachet (General) Section	0	6	7	6
2.	Liquid Ampoule & Vial (General) Section	3	7	9	10
3.	Capsule (Cephalosporin) Section	0	4	7	4

	Liquid Ampoule & Vial (General) Section: 09 product/ 07 molecule	
421.	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	Vital D3 Injection 5mg/ml
	Diary No. Date of R & I & fee	Dy.No 10773: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each 1ml Ampoule Contains: Cholecalciferol…200,000 IU
	Pharmacological Group	Vitamin D supplement
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 5's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200 000 IU / 1 ml, oral solution in ampoule by Bouchara-Recordati (**ANSM** FranceApproved)
	Me-too Status	CCL-D Injection by CCL Pharma (Reg#077118)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
422.	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	Ranit 50mg/2ml Injection
	Diary No. Date of R & I & fee	Dy.No 10768: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each 2ml Ampoule Contains: Ranitidine Hcl Eq. to Ranitidine…50mg
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 100's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Ranitidine 50mg/2ml Solution for Injection and Infusion by Alliance Pharmaceuticals (**MHRA** Approved)
	Me-too Status	New-Dine Injection by News Pharma (Reg#077156)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
423.	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	Tramasis 100mg/2ml Injection
	Diary No. Date of R & I & fee	Dy.No 10767: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each 2ml Ampoule Contains: Tramadol HCl…100mg
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification

	Pack Size & Demanded Price	5's, 10's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Tramadol 50 mg/ml solution for injection/infusion by AS KALCEKS (**MHRA** Approved)
	Me-too Status	TOMDOL Injection 100mg by Rasco Pharma (Reg#074988)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision:Approved with innovator's specification.	
424.	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	Haemofer 100mg/5ml Injection
	Diary No. Date of R & I & fee	Dy.No 10758: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each 5ml Ampoule Contains: Iron III Hydroxide Sucrose Complex eq to elemental Iron as …100mg
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack Size & Demanded Price	5's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Venofer Injection by LUITPOLD (**USFDA** Approved)
	Me-too Status	Venofer I.V. Injection of M/s Gastro Care Karachi (Reg.#023654)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision:Approved with innovator's specification.	
425.	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	Mecovit 500mcg/ml Injection
	Diary No. Date of R & I & fee	Dy.No 17404: 07-03-2019 PKR 20,000/-: 06-03-2019
	Composition	Each 1ml Ampoule Contains: Mecobalamin…500mcg
	Pharmacological Group	Vitamin B 12 analogue
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack Size & Demanded Price	10's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too Status	Flench Injection by Tabros Pharma (Reg#029050)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision:Approved with innovator's specification.	
426.	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	Vitamin B-12 1000mcg/2ml Injection
	Diary No. Date of R & I & fee	Dy.No 17410: 07-03-2019 PKR 20,000/-: 06-03-2019
	Composition	Each 2ml ampoule contains: Vitamin B12 (Cyanocobalamin)…1000mcg
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished Product Specification	JP Specs
	Pack Size & Demanded Price	25's, 100's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	B12 Steigerwald solution for injection by Bayer Vital GmbH (**Germany** Approved)
	Me-too Status	Newbal Injection by News Pharma (Reg#078919)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML

	Remarks of the Evaluator[3]	
	Decision: Approved.	
427.	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	Vitamin B-12 1000mcg/1ml Injection
	Diary No. Date of R & I & fee	Dy.No 17412: 07-03-2019 PKR 20,000/-:06-03-2019
	Composition	Each 1ml ampoule contains: Vitamin B12 (Cyanocobalamin)…1000mcg
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished Product Specification	JP Specs
	Pack Size & Demanded Price	100's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	B12 >> Ankermann << 1000 µgsolution for injection by Wörwag Pharma GmbH (**Germany** Approved)
	Me-too Status	Cyanocobalamin Injection by Amaan Pharma (Reg#094555)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
428.	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	Lincosis 600mg/2ml Ampoule
	Diary No. Date of R & I & fee	Dy.No 10779: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each 2ml Ampoule Contains: Lincomycin Hcl Monohydrate eq. to Lincomycin…600mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's, 25's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	LINCOMYCIN SXP lincomycin (as hydrochloride monohydrate) 600 mg/2 mL solution for injection ampoule by Southern Cross Pharma Pty Ltd (**TGA** Approved)
	Me-too Status	Lincomycin Injection by Amaan Pharma (Reg#087509)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
429.	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	Lincosis 600mg/2ml Vial
	Diary No. Date of R & I & fee	Dy.No 10778: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each 2ml vial Contains: Lincomycin HCl Monohydrate Eq. to Lincomycin…600mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x1's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	LINCOCIN lincomycin 600 mg/2 mL (as hydrochloride) injection vial by Pfizer Australia Pty Ltd (**TGA** Approved)
	Me-too Status	Lincomin Injection 600 mg by Elite Pharma (Reg#080198)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
Sachet (General) Section: 07 product/ 06 molecule		
430.	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	Ruler Insta 20mg Sachet
	Diary No. Date of R & I & fee	Dy.No 10777: 05-03-2019 PKR 20,000/-: 05-03-2019

	Composition	Each sachet contains: Omeprazole….....20mg sodium bicarbonate…....1680mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 14's, 20's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Zegerid powder for oral suspension by Santarus Inc. (**USFDA** Approved)
	Me-too Status	Risek Insta Sachet 20mg+1680mg by Getz Pharma (Reg#058547)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
431.	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	Ruler Insta 40mg Sachet
	Diary No. Date of R & I & fee	Dy.No 10757: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each sachet contains: Omeprazole…40mg sodium bicarbonate…1680mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 14's, 20's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Zegerid powder for oral suspension by Santarus Inc. (**USFDA** Approved)
	Me-too Status	Risek Insta Sachet 40mg + 1680mg by Getz Pharma (Reg#058548)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
432.	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	Limka-Soda Sachet
	Diary No. Date of R & I & fee	Dy.No 17403: 07-03-2019 PKR 20,000/-:06-03-2019
	Composition	Each Sachet Contains: Sodium bicarbonate…1.716g Sodium citrate…0.613g Citric Acid…0.702g Tartaric Acid…0.858g
	Pharmacological Group	Antacid and anti-flatulent
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack Size & Demanded Price	10's, 20's, 50's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Could not be confirmed in the exact strength
	Me-too Status	Citro soda sachet by Abbott
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	Following TGA approved product was quoted by the firm URACOL Effervescent Granules oral powder sachet citric acid…….. 720 mg sodium bicarbonate ……..1.76 g sodium citrate……630 mg tartaric acid……890 mg Registration Board has already approved case of Martin Dow

		for a product Lemo Soda Sachet 4gm on the basis of me-too status because the formulation is considered OTC in various authorities. The approved product of Martin Dow contains tartaric acid 0.856gm
	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.	
433.	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	Oasis Sachet
	Diary No. Date of R & I & fee	Dy.No 17397: 07-03-2019 PKR 20,000/-:06-03-2019
	Composition	Each Sachet Contains: Sodium Chloride…2.6g Potassium Chloride…1.5g Sodium citrate Dihydrate…2.9g Glucose…13.5g
	Pharmacological Group	Oral rehydration therapy
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	10's, 20's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	WHO recommended low osmolarity formula
	Me-too Status	Omene ORS Sachet by Winthrox (Reg#080538)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
434.	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	Smecdral Sachet
	Diary No. Date of R & I & fee	Dy.No 17409: 07-03-2019 PKR 20,000/-: 06-03-2019
	Composition	Each Sachet Contains: Dioctahedral Smectite…3g
	Pharmacological Group	Other intestinal adsorbents
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack Size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	ANSM approved
	Me-too Status	G-SMECTA Sachet by GT Pharma (Reg#080688)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision:Approved with innovator's specification.	
435.	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	ORS Sachet
	Diary No. Date of R & I & fee	Dy.No 17405: 07-03-2019 PKR 20,000/-: 06-03-2019
	Composition	Each Sachet Contains: Sodium Chloride…1.3g Potassium Chloride…0.75g Sodium citrate Dihydrate…1.45g Glucose…6.75g
	Pharmacological Group	Oral rehydration therapy
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	10's, 20's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Low osmolar sachet for reconstitution in ½ Liter

	Me-too Status	Winlyt Sachet by Winthrox
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
436.	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	Avezole Insta 20mg Sachet
	Diary No. Date of R & I & fee	Dy.No 10761: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each Sachet Contains: Enteric coated granules of esomeprazole magnesium trihydrate eq. to esomeprazole…20mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack Size & Demanded Price	10's, 14's, 20's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Nexium 20mg Sachet by Astrazaneca (**USFDA** Approved)
	Me-too Status	Somezol 40mg Sachet by Bosch Pharma (Reg#081612)
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
Capsule (Cephalosporin) Section: 07 product/ 04 molecule		
437.	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 200mg Capsule
	Diary No. Date of R & I & fee	Dy.No 10769: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each Capsule Contains: Cefixime as Cefixime Trihydrate…200mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	JP Specs
	Pack Size & Demanded Price	5's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Spain approved
	Me-too Status	Cefim capsule by Hilton
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
438.	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 400mg Capsule
	Diary No. Date of R & I & fee	Dy.No 10784: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each Capsule Contains: Cefixime as Cefixime Trihydrate…400mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	JP Specs
	Pack Size & Demanded Price	5's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Spain approved
	Me-too Status	Cefim capsule by Hilton
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	

439.	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	Avadrox 500mg Capsule
	Diary No. Date of R & I & fee	Dy.No 10759: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each Capsule Contains: Cefadroxil Monohydrate eq. to Cefadroxil…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	12's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	MHRA Approved
	Me-too Status	Evacef Capsules 500mg by Highnoon
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
440.	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	Viocef 250mg Capsule
	Diary No. Date of R & I & fee	Dy.No 17414: 07-03-2019 PKR 20,000/-: 06-03-2019
	Composition	Each Capsule Contains: Cefradine as Cefradine Monohydrate…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	MHRA Approved
	Me-too Status	Velosef capsule
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
441.	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	Viocef 500mg Capsule
	Diary No. Date of R & I & fee	Dy.No 17398: 07-03-2019 PKR 20,000/-:06-03-2019
	Composition	Each Capsule Contains: Cefradine as Cefradine Monohydrate…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	MHRA Approved
	Me-too Status	Velosef capsule
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
442.	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	Avalex 250mg Capsule
	Diary No. Date of R & I & fee	Dy.No 10755: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each Capsule Contains: Cephalexin Monohydrate Eq. to Cephalexin…250mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack Size & Demanded Price	12's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Keflex Capsule by Pragma (**USFDA** Approved)
	Me-too Status	Kix Capsule by Linta Pharma
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	
443.	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	Avalex 500mg Capsule
	Diary No. Date of R & I & fee	Dy.No 10764: 05-03-2019 PKR 20,000/-: 05-03-2019
	Composition	Each Capsule Contains: Cephalexin Monohydrate Eq. to Cephalexin…500mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Keflex Capsule by Pragma (**USFDA** Approved)
	Me-too Status	Kix Capsule by Linta Pharma
	GMP Status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Remarks of the Evaluator[3]	
	Decision: Approved.	

Case No. 03: Registration Applications of Categories to be Considered on Priority

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

444.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories (Pvt) Ltd. 28th KM Ferozepur Road Lahore
	Brand Name +Dosage Form+ Strength	Tamoxen Tablet 20mg
	Composition	Each tablet contains: Tamoxifen (as citrate)……..20mg
	Diary No. Date of R& I & fee	Dy No. 40263: 05-12-2018 PKR 20,000/-: 05-12-2018
	Pharmacological Group	Anti-estrogens (L02BA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TAMOXIFEN CITRATE20mg Tablet (**USFDA** Approved)
	Me-too status	Tamoxifen-Sandoz 20mg Tablet by Novartis
	GMP status	Last inspection report 01-8-2017 with conclusion that panel Recommended issuance of GMP certificate to the firm.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
445.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals, 3Km Murghzar Road, Saidu Sharif Swat Pakistan
	Brand Name+Dosage Form + Strength	Shetrozole Tablet 2.5mg
	Composition	Each film coated tablet contains: Letrozole…….2.5mg
	Diary No. Date of R& I & fee	Dy No. 39883: 04-12-2018 PKR 20,000/-: 04-12-2018
	Pharmacological Group	Aromatase Inhibitor (L02BG)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Femara 2.5mg Tablet by Novartis (**MHRA** Approved)
	Me-too status	Femara 2.5mg Tablet by Novartis
	GMP status	Last GMP inspection conducted on 13-09-2018and the report concludes that overall the firm was found to be GMP compliant.
	Remarks of the Evaluator[3]	•
	Decision: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.	
446.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals, 3Km Murghzar Road, Saidu Sharif Swat Pakistan
	Brand Name +Dosage Form + Strength	Carolimus Tablet 5mg
	Composition	Each Tablet contains: Everolimus……5mg
	Diary No. Date of R& I & fee	Dy No. 39889: 04-12-2018 PKR 20,000/-: 04-12-2018
	Pharmacological Group	Selective immunosuppressant (L04AA)
	Type of Form	Form 5
	Finished Product Specification	Innovator's
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Linevero 5mg Tablet by Ethypharm (**MHRA** Approved)
	Me-too status	Afinitor 5mg Tablet by Novartis
	GMP status	Last GMP inspection conducted on 13-09-2018 and the report concludes that overall the firm was found to be GMP compliant.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
447.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals, 3Km Murghzar Road, Saidu Sharif Swat Pakistan
	Brand Name +Dosage Form + Strength	Shamoxifen Tablet 10mg
	Composition	Each film coated tablet contains: Tamoxifen (as citrate)……..10mg
	Diary No. Date of R& I & fee	Dy No. 39884: 04-12-2018 PKR 20,000/-: 04-12-2018
	Pharmacological Group	Anti-estrogens (L02BA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nolvadex 10mg Tablet by Astrazaneca (**MHRA** Approved)
	Me-too status	Tamoxifen-Sandoz Tablet by Novartis
	GMP status	Last GMP inspection conducted on 13-09-2018 and the report concludes that overall the firm was found to be GMP compliant.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
448.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceuticals, 3Km Murghzar Road, Saidu Sharif Swat Pakistan
	Brand Name +Dosage Form + Strength	Shamoxifen Tablet 20mg
	Composition	Each film coated tablet contains: Tamoxifen (as citrate)……..20mg
	Diary No. Date of R& I & fee	Dy No. 39854: 04-12-2018 PKR 20,000/-: 04-12-2018
	Pharmacological Group	Anti-estrogens (L02BA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Nolvadex-D 20mg Tablet by Astrazaneca (**MHRA** Approved)
	Me-too status	Tamoxifen-Sandoz 20mg Tablet by Novartis
	GMP status	Last GMP inspection conducted on 13-09-2018 and the report concludes that overall the firm was found to be GMP compliant.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
449.	Name and address of manufacturer / Applicant	M/s McOlson Research Laboratories (Pvt) Ltd., 26 KM, Lahore-Sharikpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Lefnomid 20mg Tablet
	Composition	Each film coated tablet contains: Leflunomide……..20mg
	Diary No. Date of R& I & fee	Dy No. 41683: 07-12-2018 PKR 20,000/-: 07-12-2018
	Pharmacological Group	Selective immunosuppressants (L04AA)
	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	Tablet Lufid 20mg by Swiss Pharma
	GMP status	Last GMP inspection report dated 15-02-2018 declaringfollowing "General Observations": "HVAC system isproperly installed and functional in all production areas.Overall cleanliness of the plant is good. Flow of personalmovement, material movement and process is as per cGMP. The firm has sufficient production capacities formanufacturing of different products in all sections. Howeverthe firm was advised to improve documentation systemregarding validation of testing procedure and manufacturingprocedure.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
450.	Name and address of manufacturer / Applicant	M/s McOlson Research Laboratories (Pvt) Ltd., 26 KM, Lahore-Sharikpur Road Sheikhupura
	Brand Name +Dosage Form + Strength	Lefnomid 100mg Tablet
	Composition	Each film coated tablet contains: Leflunomide……..100mg
	Diary No. Date of R& I & fee	Dy No. 41684: 07-12-2018 PKR 20,000/-: 07-12-2018
	Pharmacological Group	Selective immunosuppressants (L04AA)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	3's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Aidra 100mg Tablets by Wilshire
	GMP status	Last GMP inspection report dated 15-02-2018 declaringfollowing "General Observations": "HVAC system isproperly installed and functional in all production areas.Overall cleanliness of the plant is good. Flow of personalmovement, material movement and process is as per cGMP. The firm has sufficient production capacities formanufacturing of different products in all sections. Howeverthe firm was advised to improve documentation systemregarding validation of testing procedure and manufacturingprocedure.

	Remarks of the Evaluator[3]	•
	Decision: Approved.	
451.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals Plot No. 12, Street N-3, National Industrial Zone RCCI Rawat Islamabad
	Brand Name +Dosage Form + Strength	Lefluno 100mg Tablet
	Composition	Each film coated tablet contains: Leflunomide……..100mg
	Diary No. Date of R& I & fee	Dy No. 40265: 05-12-2018 PKR 20,000/-: 05-12-2018
	Pharmacological Group	Selective immunosuppressants (L04AA)
	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	Aidra 100mg Tablets by Wilshire
	GMP status	Last GMP inspection conducted on 19-12-2017, and thereport concluded that the overall GMP compliance is Goodas of today.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	

e. EXPORT FACILITATION:

Following six cases were received from Assistant Director Reg-I vide letter No. F.7-7/2017-Reg-II (Vol-III) dated 30th April 2019. According to the contents of the letter the firm has achieved the benchmark of USD 501,457.13/- during the fiscal year 2017-18, now the firm has submitted list of 5 molecules (1 human and 4 veterinary) for consideration on priority as per the decision of 263rd meeting of Registration Board.

	Human	
452.	Name and address of manufacturer / Applicant	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Rifix 550mg Tablet
	Composition	Each film coated tablet contains: Rifaximin……550mg
	Diary No. Date of R& I & fee	Dy No. 33696: 10-10-2018 PKR 20,000/-: 09-10-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	10's. 12's, 14's, 20's, 28's, 30's: As per DPC
	Approval status of product in Reference Regulatory Authorities.	Targaxan 550mg film coated tablet by Alfasigma (**MHRA** Approved)
	Me-too status	Faxim Tablet by StandPharm
	GMP status	Last GMP inspection conducted on 19-07-2017 and the report concludes that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[3]	•
	Decision:Approved with innovator's specification.	
	Veterinary	
453.	Name and address of manufacturer / Applicant	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Hilfen Injection 300mg/ml
	Composition	Each ml contains: Florfenicol……300mg
	Diary No. Date of R& I & fee	Dy No. 34111: 15-10-2018 PKR 20,000/-: 12-10-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification

	Pack size & Demanded Price	10ml vial: Decontrolled
	Me-too status	Rivaflor 300 Injection by Mylab Pharma (Reg#078205)
	GMP status	As recorded for above application
	Remarks of the Evaluator[3]	•
	Decision:Approved with innovator's specification.	
454.	Name and address of manufacturer / Applicant	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Hilfen Injection 300mg/ml
	Composition	Each ml contains: Florfenicol……300mg
	Diary No. Date of R& I & fee	Dy No. 34112: 15-10-2018 PKR 20,000/-: 12-10-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	50ml vial: Decontrolled
	Me-too status	Flor-Vet Injection by Medivet (Reg#063546)
	GMP status	As recorded for above application
	Remarks of the Evaluator[3]	•
	Decision:Approved with innovator's specification.	
455.	Name and address of manufacturer / Applicant	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Hilfen Injection 300mg/ml
	Composition	Each ml contains: Florfenicol……300mg
	Diary No. Date of R& I & fee	Dy No. 34113: 15-10-2018 PKR 20,000/-: 12-10-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	100ml vial: Decontrolled
	Me-too status	Florofen Injection by Leads Pharma (Reg#043160)
	GMP status	As recorded for above application
	Remarks of the Evaluator[3]	•
	Decision:Approved with innovator's specification.	
456.	Name and address of manufacturer / Applicant	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Mycohil COL Liquid
	Composition	Each ml contains: Tylosin Tartrate……..100mg Doxycycline HCL…..200mg Colistin Sulfate……0.5MIU Bromhexine HCl……..5mg
	Diary No. Date of R& I & fee	Dy No. 33696: 10-10-2018 PKR 20,000/-: 09-10-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	100ml, 250ml, 1000ml: Decontrolled
	Me-too status	CRD-COL LIQUID by Attabak Pharma (Reg#058879)
	GMP status	As recorded for above application
	Remarks of the Evaluator[3]	•
	Decision:Approved with innovator's specification.	
457.	Name and address of manufacturer / Applicant	M/s Hilton Pharma (Pvt) Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Hilworm suspension
	Composition	Each ml contains: Oxfendazole……22.65mg Triclabendazole……85mg

	Diary No. Date of R& I & fee	Dy No. 33695: 10-10-2018 PKR 20,000/-: 09-10-2018
	Pharmacological Group	Anti-helmintic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	100ml, 250ml, 1000ml: Decontrolled
	Me-too status	Vorcid Suspension by Breeze Pharma (Reg#063563)
	GMP status	As recorded for above application
	Remarks of the Evaluator[3]	•
	Decision:Approved with innovator's specification.	

Case No. 04: Registration applications of import cases

a. Deferred cases

i. Human

458.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP)
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP and Sole agency agreement) **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per sole agency agreement)
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CARBOPLATIN IV Injection 100mg Freeze dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Carboplatin…….100mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	2 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 392 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Cannot be confirmed
	Me-too status	Carboplatin for injection 100mg/vial by M/s Mehran International. (Imported from China) (Reg # 052270) Carboplatin for injection 100mg/vial by PakChina International (Imported from China)(Reg # 066006)
	Detail of certificates attached	Original Legalized CoPP issued by Jining Food and Drug Administration **valid till 14/12/2017** confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Approval status of the product with strength 100mg/vial cannot be confirmed. However product with 50mg/vial,

	150mg/vial and 450mg/vial are approved by USFDA. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274):

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true
- Evidence of approval status of the product in reference regulatory authorities in the applied strength.
- Detail of diluent to be used for reconstitution.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has submitted stability study data sheets duly signed by the authorized personnel of manufacturer of 3 batches conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Evidence of approval status of the product in reference regulatory authorities in the applied strength.	Firm has not submitted any reference

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Firm has submitted evidence of USFDA **which could not be verified**
Product is present in USP and specification of pH are more stringent in USP 5-7 while your	Firm has submitted that their inner control standards (6.0-7.0) are more stringent than USP.

	claimed specification are 5.5-7.5	
	Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting** • **Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.**	
459.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP)
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP and Sole agency agreement) **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per sole agency agreement)
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CARBOPLATIN IV Injection 200mg Freeze dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Carboplatin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic agent, Platinum Containing cytotoxic
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 3562Dated 6/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 03/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Evidence of approval in Reference Regulatory Authority.
	Me-too status	Could not be confirmed
	Detail of certificates attached	Original Legalized CoPP issued by Jining Food and Drug Administration **valid till 14/12/2017** confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Detail of diluent to be used for reconstitution. • Agreement does not include the carboplatin. • Evidence of approval in Reference Regulatory Authority. • Stability data sheets of atleast 3 batches according to Zone IVA. • Valid drug sale license. • Credentials are not signed . • Certificate no is not mentioned on COPP. • Clarification of pharmacological group.

		• Mention the type of container. • Product is present in USP while finished product specifications are not as per USP. Like pH in USP is 5-7 while you have provided 5.5-7.5. • URDU version label. • Site master file or signed credentials.

Evaluation by PEC

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Firm has submitted evidence of USFDA **which could not be verified**
Product is present in USP and specification of pH are more stringent in USP 5-7 while your claimed specification are 5.5-7.5	Firm has submitted that their inner control standards (6.0-7.0) are more stringent than USP.
Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life

Decision: Deferred for following submissions:

- **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting**
- **Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.**

460.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China
	Name and address of marketing authorization holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CALCIUM FOLINATE injection 100mg Freeze dried cake for solution for IV injection (Lyophilized Powder)

Composition	Each vial contains: Calcium folinate…. 100mg
Finished Product Specification	BP
Pharmacological Group	Anti dot to folic acid antagonist/Detoxifying agent for antineoplastic treatment
Shelf life	2 years
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No. 385 Dated 16/03/2017
Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
Demanded Price	As per SRO
Pack size	1×1's
International availability	Calcium folinate powder for solution 100mg/vial by M/s Mylan, ANSM France Approved
Me-too status	Calcium flogen 100mg injection by M/s Genetech (IMPORTED from China) (Reg # 059269)
Detail of certificates attached	Original Legalized CoPP (certificate No. 20150008) issued by Shanxi Food and Drug Administration **valid till 31/08/2017** confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274):

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.
- Detail of diluent to be used for reconstitution.
- Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
- Submission of original, legalized and valid CoPP.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has submitted stability study data sheets duly signed by the authorized personnel of manufacturer of 3 batches conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Evidence of approval status of the product in reference regulatory authorities in the applied strength.	Firm has not submitted any reference
Submission of original, legalized and valid CoPP	Firm has submitted new CoPP which is valid till 26-02-2020.

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Firm has submitted evidence of USFDA **which could not be verified**
Variation in address mentioned on DSL and Form 5A. Clarify	Firm has submitted revised Form 5A
Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life

Decision: Deferred for following submissions:

- **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting**
- **Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.**

461.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China
	Name and address of marketing authorization holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CALCIUM FOLIN ATE injection 300mg Freeze Dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Calcium folinate…. 300mg
	Finished Product Specification	BP
	Pharmacological Group	Anti dot to folic acid antagonist
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 387 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017

Demanded Price	As per SRO
Pack size	1×1's
International availability	Could not be confirmed (Approved as lyophilized powder for injection 200mg/Vial & 350mg/Vial)
Me-too status	Could not be confirmed
Detail of certificates attached	Original Legalized CoPP (certificate No. 20150009) issued by Shanxi Food and Drug Administration **valid till 15/09/2017** confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Decision:

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true
- Detail of diluent to be used for reconstitution.
- Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
- Submission of original legalized and valid CoPP.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has submitted stability study data sheets duly signed by the authorized personnel of manufacturer of 3 batches conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Evidence of approval status of the product in reference regulatory authorities in the applied strength.	Firm has not submitted any reference
Submission of original, legalized and valid CoPP	Firm has submitted new CoPP which is valid till 26-02-2020.

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the

		manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
	Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Firm has submitted evidence of USFDA **which could not be verified**
	Variation in address mentioned on DSL and Form 5A. Clarify	Firm has submitted revised Form 5A
	Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life
	Decision: Deferred for following submissions: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting** • **Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.**	
462.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	Docetaxel injection 20mg Freeze dried cake for solution for injection (Lyophilized powder)
	Composition	Each Vial (0.5ml) Contains: Docetaxel…….20mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 390 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	DOCEFREZ lyophilized powder for injection (20mg/vial of 1ml, 80mg/vial of 4ml) by Ms/ Sun Pharmaceutical Ind. Ltd, USFDA Approved.
	Me-too status	Docet 20mg/0.5ml injection by M/s Helix Pharma (IMPORTED) (Reg # 072507)
	Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/62248) issued by Jining Food and Drug Administration on 14/12/2015

	confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has applied for registration with generic name. • The product is approved in USFDA as powder for injection in 1ml vial while the firm has applied with for powder for injection in 0.5ml vial. 1ml of the solvent is required for reconstitution. (Ref USFDA) and 2mg/0.5ml injection is approved in Health Canada as Solution for injection. • The firm has claimed USP specifications while the product is not present in USP/BP. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274):

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°C and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°C and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°C and 65 ± 5%RH) is not true
- Detail of diluent to be used for reconstitution.
- Evidence of approval of the product in reference regulatory authorities in the same strength/volume.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has again submitted stability data with protocol having condition 30 ± 2oC and 65 ± 5%RH and stability data with condition 25 ± 2oC and 60 ± 5%RH. This data has been verified/stamped by Cisen Pharmaceuticals. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Evidence of approval of the product inreference regulatory authorities in the same strength/ volume.	Docetaxel Actavis 20mg/0.5ml concentrate and solvent for solution for infusion**MHRA** Approved.

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
The protocols of stability mentions conditions 30 ± 2oC and 65 ± 5%RH whereas the stability data mentions the condition 25 ± 2oC and 60 ± 5%RH. The data is same as submitted before	Firm has submitted long term stability of 3 batches 1604051231, 1604051232, 1604051233. The batches were manufactured in April 2018 and the firm has submitted stability data till 36 months which should have been completed in April 2021 but the stability data sheets contains values for the time points which are yet to come.
Clarifythe formulation whether lyophilized powder or concentrate	Concentrate
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or	Firm has submitted that "as per the announcement of Shandong province food and drug administration,

	provincial certifying authority.	shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
	Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Docetaxel Actavis 20mg/0.5ml concentrate and solvent for solution for infusion**MHRA** Approved.
	Firm has claimed USP specification but impurity and endotoxin specification of USP are more stringent than provided specification.	Firm has submitted that their docetaxel injection is according to CFDA standard, but the inner controlled parameter of impurity and endotoxin is more strict than USP standard. The firm has also compared USP standard limits with their inner controlled standards.
	Decision: Registration Board deferred the case for following submission: • **Clarification of the stability study data sheets which contains the results of 3 years stability study data for batches manufactured in April 2018.** • **Submission of original signed stability study data sheets along with complete results for long term stability of 3 batches 1604051231, 1604051232 and 1604051233 which were manufactured in April 2018.**	
463.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	DOCETAXEL Injection 80 mg Freeze dried cake for solution for IV injection (lyophilized Powder)
	Composition	Each Vial (2ml) Contains: Docetaxel…….80mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 393 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	DOCEFREZ lyophilized powder for injection (20mg/vial of 1ml, 80mg/vial of 4ml) by Ms/ Sun Pharmaceutical Ind. Ltd, USFDA

	Approved.
Me-too status	Docet 80mg/2ml injection by M/s Helix Pharma (IMPORTED) (Reg # 072508)
Detail of certificates attached	Legalized copy and valid CoPP (certificate No. 171100B0/33636) issued by Jining Food and Drug Administration on 05/06/2017 confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has applied for registration with generic name. • The product is approved in USFDA as powder for injection in 4ml vial while the firm has applied with for powder for injection in 2ml vial. 4ml of the solvent is required for reconstitution. (Ref USFDA) and 80mg/2ml injection is approved in HealthCanada as Solution for injection. • The firm has claimed USP specifications while the product is not present in USP/BP. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274):

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true
- Detail of diluent to be used for reconstitution.
- Evidence of approval of the product in reference regulatory authorities in the same strength/volume/dosage form.
- Finished product specifications.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has again submitted stability data with protocol having condition 30 ± 2oC and 65 ± 5%RH and stability data with condition 25 ± 2oC and 60 ± 5%RH. This data has been verified/stamped by Cisen Pharmaceuticals. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Evidence of approval of the product inreference regulatory authorities in the same strength/volume.	Docetaxel Actavis 80mg/2ml concentrate and solvent for solution for infusion**MHRA** Approved.

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	Response by the firm
The copy of CoPP has been provided	Original, legalized CoPP was already available in the dossier. The CoPP confirm the product as 80mg/1.5ml, while 7ml vials are mentioned in the stability study data and the international reference

		was also for 80mg/2ml.
	The protocols of stability mentions conditions 30 ± 2oC and 65 ± 5%RH whereas the stability data mentions the condition 25 ± 2oC and 60 ± 5%RH. The data is same as submitted before	Firm has submitted long term stability of 3 batches 1608231231, 1608231232, 1608231233. The batches were manufactured in August 2018 and the firm has submitted stability data till 36 months which should have been completed in August 2021 but the stability data sheets contains values for the time points which are yet to come.
	The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
	Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Docetaxel Actavis 80mg/2ml concentrate MHRA Approved, but the product mentioned in CoPP is 80mg/1.5ml
	Firm has claimed USP specification but impurity and endotoxin specification of USP are more stringent than provided specification.	Firm has submitted that their docetaxel injection is according to CFDA standard, but the inner controlled parameter of impurity and endotoxin is more strict than USP standard. The firm has also compared USP standard limits with their inner controlled standards.
	Decision: Registration Board deferred the case for following submission: • **Clarification of the stability study data sheets which contains the results of 3 years stability study data for batches manufactured in August 2018.** • **Submission of original signed stability study data sheets along with complete results for long term stability of 3 batches 1608231231, 1608231232 and 1608231233 which were manufactured in August 2018.** • **Clarification regarding the fill volume, since the CoPP confirms that the product is 80mg/1.5ml, while in stability study data 7ml vials are mentioned. Furthermore the MHRA approved reference product contains 80mg/2ml.**	
464.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China.
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. (as per CoPp and Sole agency agreement) **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per sole agency agreement)
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	Oxaliplatin for injections 50mg Freeze dried cake for solution for IV injections (lyophilized)
	Composition	Each Vial Contains:

	Oxaliplatin….. 50mg
Finished Product Specification	In House
Pharmacological Group	Antineoplastic
Shelf life	3 years
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No. 383 Dated 16/03/2017
Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
Demanded Price	As per SRO
Pack size	1×1's (7ml glass vial)
International availability	ELOXATIN for injection (50mg 100mg) by M/s SANOFI AVENTIS US, **USFDA** approved
Me-too status	Celdach 50 injection by Hakimsons (Reg # 72565) 64
Detail of certificates attached	Original Legalized CoPP (certificate No. 151100B0/47076) issued by Jining Food and Drug Administration on 16/09/2015 is attached which confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has claimed In House manufacturing specifications while the product is available in USP. As per USP the product contains Oxaliplatin and Lactose monohydrate while according to formulation provided by the firm the product contains Oxaliplatin and Mannitol. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter, firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274):

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.
- Detail of diluent to be used for reconstitution.
- Clarification regarding formulation since USP specifies the formulation containing Oxaliplatin with Lactose monohydrate while submitted formulation by you contains Oxaliplatin and Mannitol.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has submitted stability study data sheets duly signed by the authorized personnel of manufacturer of 3 batches 170610, 170611, 170612 conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. Additionally the impurities identified at various time points exceeds the limit identified in acceptance criteria i.e. NMT 0.2%. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.

Clarification regarding formulation since USP specifies the formulation containing Oxaliplatin with Lactose monohydrate while submitted formulation by you contains Oxaliplatin and Mannitol	Firm has submitted that their principle manufacturer has informed that China FDA does not approved lactose as excipient of lyophilized powder instead they accept mannitol because it provides more stability.

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Eloxatin Injection 50mg by M/s Sanofi Aventis Inc USA. (**USFDA** Approved)
According to the specification of related substances any individual impurity specs in NMT 0.2%. However the results are greater than 0.2% i.e. out of specs, clarification is required.	Firm has submitted specifications of oxaliplatin and comparison of its specs with USP and inner control standards but the firm has **NOT** submitted justification of their results outside the acceptance criteria.
Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life

Decision: Deferred for following submissions:

- **Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.**
- **Scientific justification for out of specification impurities (i.e. results greater than 0.2%) while the acceptance criteria was NLT 0.2%.**

465.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	**Address:** Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. **Validity:** 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China.
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. (as per CoPP and Sole agency agreement) **Exporting agent for Pakistan:** M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per Sole Agency Agreement)
	Name of exporting country	China

Brand Name +Dosage Form + Strength	OXALIPLATIN for injections 100mg Freeze dried cake for solution for IV injections (lyophilized)
Composition	Each Vial Contains: Oxaliplatin….. 100mg
Finished Product Specification	In House
Pharmacological Group	Antineoplastic
Shelf life	3 years
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No. 398 Dated 16/03/2017
Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
Demanded Price	As per SRO
Pack size	1×1's
International availability	ELOXATIN for injection (50mg 100mg) by M/s SANOFI AVENTIS US, USFDA approved
Me-too status	Celdach 50 injection by Hakimsons (Reg # 72564)
Detail of certificates attached	Original Legalized CoPP (certificate No. 151100B0/47077) issued by Jining Food and Drug Administration on 16/09/2015 is attached which confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has claimed In House manufacturing specifications while the product is available in USP. As per USP the product contains Oxaliplatin and Lactose monohydrate while according to formulation provided by the firm the product contains Oxaliplatin and Manitol. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274):

The Registration Board deferred the cases for;

- Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.
- Detail of diluent to be used for reconstitution.
- Clarification regarding formulation since USP specifies the formulation containing Oxaliplatin with Lactose monohydrate while submitted formulation by you contains Oxaliplatin and Mannitol.

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has submitted stability study data sheets duly signed by the authorized personnel of manufacturer of 3 batches 170613, 170614, 170615 conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. Additionally the impurities identified at various time points exceeds the limit identified in acceptance criteria i.e. NMT 0.2%. The firm has **NOT** submitted any clarification regarding already submitted stability data sheets having same values at both conditions.

Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Clarification regarding formulation since USP specifies the formulation containing Oxaliplatin with Lactose monohydrate while submitted formulation by you contains Oxaliplatin and Mannitol	Firm has submitted that their principle manufacturer has informed that China FDA does not approved lactose as excipient of lyophilized powder instead they accept mannitol because it provides more stability.

After the evaluation of the response, another letter of shortcoming No. F.1-1/2017/PEC-DRAP(AD PEC-V) was issued by dated 23-11-2018. Now the response of the firm against that letter is also received.

Shortcomings	**Response by the firm**
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Eloxatin Injection 100mg by M/s Sanofi Aventis Inc USA. (**USFDA** Approved)
According to the specification of related substances any individual impurity specs in NMT 0.2%. However the results are greater than 0.2% i.e. out of specs, clarification is required.	Firm has submitted specifications of oxaliplatin and comparison of its specs with USP and inner control standards but the firm has **NOT** submitted justification of their results outside the acceptance criteria.
Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life

Decision: Deferred for following submissions:

- **Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.**
- **Scientific justification for out of specification impurities (i.e. results greater than 0.2%) while the acceptance criteria was NLT 0.2%.**

ii. Veterinary

466.	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. **Validity:** 13-11-2019 **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: 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. • 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. 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 of 288th meeting of Registration Board:

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

Evaluation by PEC:

Firm has submitted revised Form 5-A with address of manufacturer as per CoPP and sole agency agreement

Decision:Approved with BP specifications as per Policy for inspection of manufacturer abroad.

467.	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. **Validity:** 13-11-2019 **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: Lincomycin (as hydrochloride)……..50mg 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. • Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted. • 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. 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 30°C and 65% RH. The batches were manufactured in 2012.
	Decision of 288th meeting of Registration Board: Deferred for revision of Form5A for manufacturer revised agreement with Marketing authorization holder as per CoPP	
	Evaluation by PEC: Firm has submitted revised Form 5-A with address of manufacturer as per CoPP and sole agency agreement	
	Decision: Approved with Innovator's specifications as per Policy for inspection of manufacturer abroad.	

468.	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. **Validity:** 13-11-2019 **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: 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. • Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted. • 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	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

	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.	International is allowed to export the product for which Alfasan Nederland BV is the registration holder. 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 30°C and 65% RH.
	Firm has submitted that the manufacturer has performed stability testing as per BP monograph	
	Decision of 288th meeting of Registration Board: Deferred for revision of Form5A for manufacturer revised agreement with Marketing authorization holder as per CoPP	
	Evaluation by PEC: Firm has submitted revised Form 5-A with address of manufacturer as per CoPP and sole agency agreement	
	Decision:Approved with BP specifications as per Policy for inspection of manufacturer abroad.	
469.	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. **Validity:** 13-11-2019 **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: 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. • Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also

		submitted. • 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. 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 30°C 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. The results of pH at all-time points were within the USP limits.

Decision of 288th meeting of Registration Board:

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

Evaluation by PEC:

Firm has submitted revised Form 5-A with address of manufacturer as per CoPP and sole agency agreement

Decision:Approved with USP specifications as per Policy for inspection of manufacturer abroad.

470.	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. **Validity:** 13-11-2019 **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: Vitamin A…..15,000 IU

	Cholecalciferol….1000 IU Alfa-tocoferol acetate……20mg Thiamine hydrochloride……10mg Riboflavine sodium phosphate……6.85mg Pyridoxine hydrochloride……..3mg Cyanocobalamine……50 mcg Nicotinamide……35mg 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
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. • Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted. • 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. 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 30°C and 65% RH. The batches were manufactured in 2012.
Me-too status	Firm has submitted following me-too Multivor (Reg#048151) of ICI Pakistan This me-too could **NOT** be confirmed since the claimed me-too contains different strength of riboflavin and cyanocobalamin

Decision of 288th meeting of Registration Board:

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

	Evaluation by PEC: Firm has submitted revised Form 5-A with address of manufacturer as per CoPP and sole agency agreement. The me-too status of this formulation could **not be** confirmed	
	Decision:Approved with innovator's specifications as per Policy for inspection of manufacturer abroad.	
471.	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. **Validity:** 13-11-2019 **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: 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. • Copy of GMP certificate of M/s Alfasan International issued by Medicine Evaluation Board dated 1 and 2 February 2017 is also submitted. • 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. 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 **only 2** batches conducted at 35°C and 65% RH
	Decision of 288th meeting of Registration Board: 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	
	Evaluation by PEC: Firm has submitted revised Form 5-A with address of manufacturer as per CoPP and sole agency agreement. Firm has **not** submitted stability study data of 3rd batch	
	Decision:Deferred for the Submission of long term stability studies conducted under the conditions of zone IV-A of 3rdbatch till the complete shelf life.	

Case No. 05: 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 GMP Inspection Report Date & Remarks
472.	M/s Genix Pharma (Pvt) Ltd., 44, 45-B, Korangi Creek Road, Karachi	Carlep Tablets 200mg Each tablet contains: Eslicarbazepine acetate……200mg (Anti-epileptic)	Form 5-D Dy No. 351 14-3-2016 PKR 50,000/- (14-3-2016) 10's, 20's, 30's: Rs. 2250/ tablet	Aptiom Tablets by Sunovion Pharms **(USFDA** Approved) Last inspection report dated 8.8.2017 confirms satisfactory compliance to GMP
	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.# 17881 dated 15-5-2018)**			

STABILITY STUDY DATA	
Drug	Carlep Tablets 200mg
Name of Manufacturer	M/s Genix Pharma (Pvt) Ltd., 44, 45-B, Korangi Creek Road, Karachi
Manufacturer of API	Ami Lifesciences Pvt. Ltd., Block No. 82/B, ECP Road, AT & Post Karakhadi, Tal Padra, City Karakhadi, District: Vadodara Gujrat State, India.
API Lot No.	ECA/50010117
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks) Real Time: 0, 1, 2, 3, 4, 6, 8 (Months)		
Batch No.	TR001	TR002	TR003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2017	06-2017	06-2017
Date of Initiation	10-7-2017	10-7-2017	10-7-2017
No. of Batches	03		
Date of Submission	**Dy.# 17881 dated 15-5-2018**		

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.	Firm has submitted copy of GMP certificate of M/s Ami Lifesciences Pvt. Ltd., Block No. 82/B, ECP Road, AT & Post Karakhadi, Tal Padra, City Karakhadi, District: Vadodara Gujrat State, India. Valid till 26-4-2019 issued by Food and Drugs Control Administration Gujrat 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.	Firm has submitted ADC attested commercial invoice dated 24-2-2017confirming import of 3 Kg Eslicarbazepine acetate. The commercial invoice contains the address of head office of the firm.
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

Shortcoming communicated	Response by the firm
Justify the partial mode of testing i.e. without dissolution and assay at 1st and 3rd months in real time stability study data of all the three batches.	Firm has submitted that they have performed stability studies as per guidelines of Registration Board. The guidelines of Registration Board in 251st meeting specify weekly testing intervals while firm has used monthly testing intervals and claimed that they are following guidelines of Registration Board.
Justify the specifications of dissolution (i.e. NLT 80% of the labeled amount in 45 minutes) submitted under finished product specification, since the reference product approved by USFDA Aptiom Tablets have updated the dissolution specification for 200	Firm has submitted that as per correspondence document by CDER "*it seems to be unacceptableof dissolution criteria Q at 15 minutes as mentioned*". Firm has also provided a reference link for this data https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022416Orig1s000AdminCorres.pdf

mg strength, to a single point **Q*** at 15 minutes since its dissolution profile was not-similar to the appropriate comparator as specified in the executive summary of the chemistry review for NDA 22416 (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/022416Orig1s000ChemR.pdf). For elaboration on the value of **"Q"** FDA in its draft guidance for industry on dissolution testing of immediate release solid oral dosage forms under "setting dissolution specifications" have recommended "for highly soluble and rapidly dissolving drug products (BCS classes 1 and 3), a single-point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less is sufficient as a routine quality control test for batch-to-batch uniformity" (Ref: https://www.fda.gov/downloads/drugs/guidances/ucm070237.pdf)	As per the details of the reference shared the exact recommendations from FDA is "Your proposal for a dissolution acceptance criterion of Q= at 15 minutes for the 200 mg tablets is not acceptable. Based on the provided data, a dissolution acceptance criterion of Q= at 15 minutes is appropriate. Nevertheless, it must be recognized that some batches may require Stage 2 and, occasionally, Stage 3 testing. Revise you dissolution acceptance criterion for the 200 mg tablets from Q= at 15 minutes to Q at 15 minutes, and submit a revised specifications table for the drug product." Firm has submitted a reference of EDQM http://www.edqm.eu/en/Helpdesk-1683.html?rubrique=801 which specifies that in most of the cases Q can be 75% and overall dissolution limit can be 80% (Q+5). Since the reference product is FDA approved and upon approval the firm will be granted "innovator's specification" therefore the guidelines of FDA should be implemented for this product.

Decision of previous meetings of Registration Board:

Registration Board after thorough discussion decided to reject the stability data on the basis of following reasons:

- Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in 15 minutes.
- Results of dissolution below 85% in 45 minutes at various time intervals.
- Registration Board further directed the firm to repeat the stability studies as per the recommendations laid down in 278th meeting and finished product specifications as per the approved reference / innovator product. (**M-284)**

Registration Board deferred the above cases of Carlep Tablets 200mg, 400mg and 800mg forfurther deliberation. (**M-286)**

Registration Board after thorough discussion decided to defer the applications of Carlep Tablets 200mg, 400mg and 800mg on the basis of following reasons:

- Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while theFDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in45 minutes.
- Results of dissolution below 85% in 45 minutes at various time intervals.(**M-287)**

Firm's Reply:

- Firm has referred tofollowing literature:

i. CDER review of reference product approved by USFDA which declares that BCS class of drug Eslicarbazepine Acetate is not established while Eslicarbazepine Acetate has very low aqueous solubility.

ii. Following text from Section 6.1 (Immediate release dosage forms) of USP chapter <1092> (The Dissolution Procedure; Development and Validation)
"Although release and stability data are collected during dosage form development, it is common to record the entire dissolution profile or the amount of drug dissolved at specified intervals, such as 10, 20, 30, 40, 50, and 60 min or 15, 30, 45, and 60 min. At registration, dissolution for an immediate-release tablet usually becomes a single-point test. The acceptance criterion and test time are established by evaluating the dissolution profile data. The acceptance criterion for a dissolution test is a function of Q, which Is expressed as a percentage of label claim of drug dissolved at a specified time. Typical Q values are in the range of 75%-80% dissolved. Q values in excess of 80% are not generally used because allowance needs to be made for assay and content uniformity ranges."

iii. Following text of a review article titled as "Pharmacokinetics & Drug interactions of Eslicarbazepine acetate":
"Therefore, Eslicarbazepine Acetate is a highly permeable-poorly soluble (BCS class II), drug, whereas Eslicarbazepine is a highly soluble-highly permeable (BCS class I) drug.

- Moreover firm has submitted as under:

a. Practically we performed BCS class identification tests, material does not belong to BCS Class I.
b. Due to low solubility of drug dissolution limit Not less than 80% and as per USP General Chapter, <1092> Q-values in the range of 75% to 80%.

Firm has submitted that they have performed dissolution as per FDA dissolution method and the time point is 45 minutes that was published on 27-8-2015 while the reference stated by PEC was published in 2013, so we followed the later one. On the other hand if any product doesn't include in pharmacopoeia then we generally follow USP<1092>, the acceptance criteria for a dissolution is a function of Q which is expressed as a percentage of labeled of drug dissolved a specific time Q value in range of 75% to 80%.

Decision: Registration Board after thorough discussion decided to reject the application "Carelp Tablet 200mg" on the basis of following reasons:

- **Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in 15 minutes.**
- **Results of dissolution below 85% in 15 minutes at various time intervals.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
473.	M/s Genix Pharma (Pvt) Ltd., 44, 45-B, Korangi Creek Road, Karachi	Carlep Tablets 400mg Each tablet contains: Eslicarbazepine acetate……400mg (Anti-epileptic)	Form 5-D Dy No. 246 18-2-2016 PKR 50,000/- (18-2-2016) 10's, 20's, 30's: Rs 2500 / tablet	Aptiom Tablets by Sunovion Pharms **(USFDA** Approved) Last inspection report dated 8.8.2017 confirms satisfactory compliance to GMP

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.# 15519 dated 26-4-2018)

STABILITY STUDY DATA

Drug	Carlep Tablets 400mg		
Name of Manufacturer	M/s Genix Pharma (Pvt) Ltd., 44, 45-B, Korangi Creek Road, Karachi		
Manufacturer of API	Ami Lifesciences Pvt. Ltd., Block No. 82/B, ECP Road, AT & Post Karakhadi, Tal Padra, City Karakhadi, District: Vadodara Gujrat State, India.		
API Lot No.	ECA/50010117		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks) Real Time: 0, 1, 2, 3, 4, 6, 8 (Months)		
Batch No.	TR001	TR002	TR003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2017	06-2017	06-2017
Date of Initiation	10-7-2017	10-7-2017	10-7-2017

No. of Batches	03
Date of Submission	**Dy.# 17881 dated 15-5-2018**

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.	Firm has submitted copy of GMP certificate of M/s Ami Lifesciences Pvt. Ltd., Block No. 82/B, ECP Road, AT & Post Karakhadi, Tal Padra, City Karakhadi, District: Vadodara Gujrat State, India. Valid till 26-4-2019 issued by Food and Drugs Control Administration Gujrat 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.	Firm has submitted ADC attested commercial invoice dated 24-2-2017 confirming import of 3 Kg Eslicarbazepine acetate. The commercial invoice contains the address of head office of the firm.
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

Shortcoming communicated	Response by the firm
Justify the partial mode of testing i.e. without dissolution and assay at 1st and 3rd months in real time stability study data of all the three batches.	Firm has submitted that they have performed stability studies as per guidelines of Registration Board. The guidelines of Registration Board in 251st meeting specify weekly testing intervals while firm has used monthly testing intervals and claimed that they are following guidelines of Registration Board.
Justify the specifications of dissolution (i.e. NLT 80% of the labeled amount in 45 minutes) submitted under finished product specification, since FDA in its draft guidance for industry on dissolution testing of immediate release solid oral dosage forms under "setting dissolution specifications" have recommended "for highly soluble and rapidly dissolving drug products (BCS classes 1 and 3), a single-point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less is sufficient as a routine quality control test for batch-to-batch uniformity" (Ref: https://www.fda.gov/downloads/drugs/guidances/ucm070237.pdf).	Firm has submitted a reference of EDQM http://www.edqm.eu/en/Helpdesk-1683.html?rubrique=801 which specifies that in most of the cases Q can be 75% and overall dissolution limit can be 80% (Q+5). Since the reference product is FDA approved and upon approval the firm will be granted "innovator's specification" therefore the guidelines of FDA should be implemented for this product.

Decision of previous meetings of Registration Board:

Registration Board after thorough discussion decided to reject the stability data on the basis of following reasons:

- Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in 15 minutes.
- Results of dissolution below 85% in 45 minutes at various time intervals.
- Registration Board further directed the firm to repeat the stability studies as per the recommendations laid down in 278th meeting and finished product specifications as per the approved reference / innovator product. (**M-284)**

Registration Board deferred the above cases of Carlep Tablets 200mg, 400mg and 800mg forfurther deliberation. (**M-286)**

Registration Board after thorough discussion decided to defer the applications of Carlep Tablets 200mg, 400mg and 800mg on the basis of following reasons:

- Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in45 minutes.
- Results of dissolution below 85% in 45 minutes at various time intervals.(**M-287)**

Firm's Reply:

- Firm has referred tofollowing literature:

iv. CDER review of reference product approved by USFDA which declares that BCS class of drug Eslicarbazepine Acetate is not established while Eslicarbazepine Acetate has very low aqueous solubility.

v. Following text from Section 6.1 (Immediate release dosage forms) of USP chapter <1092> (The Dissolution Procedure; Development and Validation)
"Although release and stability data are collected during dosage form development, it is common to record the entire dissolution profile or the amount of drug dissolved at specified intervals, such as 10, 20, 30, 40, 50, and 60 min or 15, 30, 45, and 60 min. At registration, dissolution for an immediate-release tablet usually becomes a single-point test. The acceptance criterion and test time are established by evaluating the dissolution profile data. The acceptance criterion for a dissolution test is a function of Q, which Is expressed as a percentage of label claim of drug dissolved at a specified time. Typical Q values are in the range of 75%-80% dissolved. Q values in excess of 80% are not generally used because allowance needs to be made for assay and content uniformity ranges."

vi. Following text of a review article titled as "Pharmacokinetics & Drug interactions of Eslicarbazepine acetate":
"Therefore, Eslicarbazepine Acetate is a highly permeable-poorly soluble (BCS class II), drug, whereas Eslicarbazepine is a highly soluble-highly permeable (BCS class I) drug.

- Moreover firm has submitted as under:

c. Practically we performed BCS class identification tests, material does not belong to BCS Class I.

d. Due to low solubility of drug dissolution limit Not less than 80% and as per USP General Chapter, <1092> Q-values in the range of 75% to 80%.

Firm has submitted that they have performed dissolution as per FDA dissolution method and the time point is 45 minutes that was published on 27-8-2015 while the reference stated by PEC was published in 2013, so we followed the later one. On the other hand if any product doesn't include in pharmacopoeia then we generally follow USP<1092>, the acceptance criteria for a dissolution is a function of Q which is expressed as a percentage of labeled of drug dissolved a specific time Q value in range of 75% to 80%.

Decision: Registration Board after thorough discussion decided to reject the application "Carelp Tablet 400mg" on the basis of following reasons:

- **Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in 45 minutes.**
- **Results of dissolution below 85% in 45 minutes at various time intervals.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
474.	M/s Genix Pharma (Pvt) Ltd., 44, 45-B, Korangi Creek Road, Karachi	Carlep Tablets 800mg Each tablet contains: Eslicarbazepine acetate……800mg (Anti-epileptic)	Form 5-D Dy No. 238 18-2-2016 PKR 50,000/- (18-2-2016) 10's, 20's, 30's: Rs 3000/ tablet	Aptiom Tablets by Sunovion Pharms **(USFDA** Approved) Last inspection report dated 8.8.2017 confirms satisfactory compliance to GMP

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.# 15519 dated 26-4-2018)

STABILITY STUDY DATA

Drug	Carlep Tablets 800mg		
Name of Manufacturer	M/s Genix Pharma (Pvt) Ltd., 44, 45-B, Korangi Creek Road, Karachi		
Manufacturer of API	Ami Lifesciences Pvt. Ltd., Block No. 82/B, ECP Road, AT & Post Karakhadi, Tal Padra, City Karakhadi, District: Vadodara Gujrat State, India.		
API Lot No.	ECA/50010117		
Description of Pack (Container closure system)	Alu-Alu blister packed in unit carton		
Stability Storage Condition	Real time: 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks) Real Time: 0, 1, 2, 3, 4, 6, 8 (Months)		
Batch No.	TR001	TR002	TR003
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2017	06-2017	06-2017
Date of Initiation	10-7-2017	10-7-2017	10-7-2017
No. of Batches	03		
Date of Submission	**Dy.# 17881 dated 15-5-2018**		

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.	Firm has submitted copy of GMP certificate of M/s Ami Lifesciences Pvt. Ltd., Block No. 82/B, ECP Road, AT & Post Karakhadi, Tal Padra, City Karakhadi, District: Vadodara Gujrat State, India. Valid till 26-4-2019 issued by Food and Drugs Control Administration Gujrat 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	Yes

	respective documents like chromatograms, laboratory reports, data sheets etc.	
5.	Documents confirming import of API etc.	Firm has submitted ADC attested commercial invoice dated 27-4-2017 confirming import of 7 Kg Eslicarbazepine acetate. The commercial invoice contains the address of head office of the firm.
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

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Shortcoming communicated	**Response by the firm**
Justify the partial mode of testing i.e. without dissolution and assay at 1st and 3rd months in real time stability study data of all the three batches.	Firm has submitted that they have performed stability studies as per guidelines of Registration Board. The guidelines of Registration Board in 251st meeting specify weekly testing intervals while firm has used monthly testing intervals and claimed that they are following guidelines of Registration Board.
Justify the specifications of dissolution (i.e. NLT 80% of the labeled amount in 45 minutes) submitted under finished product specification, since FDA in its draft guidance for industry on dissolution testing of immediate release solid oral dosage forms under "setting dissolution specifications" have recommended "for highly soluble and rapidly dissolving drug products (BCS classes 1 and 3), a single-point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less is sufficient as a routine quality control test for batch-to-batch uniformity" (Ref: https://www.fda.gov/downloads/drugs/guidances/ucm070237.pdf).	Firm has submitted a reference of EDQM http://www.edqm.eu/en/Helpdesk-1683.html?rubrique=801 which specifies that in most of the cases Q can be 75% and overall dissolution limit can be 80% (Q+5). Since the reference product is FDA approved and upon approval the firm will be granted "innovator's specification" therefore the guidelines of FDA should be implemented for this product.

Decision of previous meetings of Registration Board:

Registration Board after thorough discussion decided to reject the stability data on the basis of following reasons:

- Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in 15 minutes.
- Results of dissolution below 85% in 45 minutes at various time intervals.
- Registration Board further directed the firm to repeat the stability studies as per the recommendations laid down in 278th meeting and finished product specifications as per the approved reference / innovator product. (**M-284)**

Registration Board deferred the above cases of Carlep Tablets 200mg, 400mg and 800mg forfurther deliberation. (**M-286)**

Registration Board after thorough discussion decided to defer the applications of Carlep Tablets 200mg, 400mg and 800mg on the basis of following reasons:

- Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in45 minutes.
- Results of dissolution below 85% in 45 minutes at various time intervals. (**M-287)**

Firm's Reply:

- Firm has referred tofollowing literature:

vii. CDER review of reference product approved by USFDA which declares that BCS class of drug Eslicarbazepine Acetate is not established while Eslicarbazepine Acetate has very low aqueous solubility.

viii. Following text from Section 6.1 (Immediate release dosage forms) of USP chapter <1092> (The Dissolution Procedure; Development and Validation)
"Although release and stability data are collected during dosage form development, it is common to record the entire dissolution profile or the amount of drug dissolved at specified intervals, such as 10, 20, 30, 40, 50, and 60 min or 15, 30, 45, and 60 min. At registration, dissolution for an immediate-release tablet usually becomes a single-point test. The acceptance criterion and test time are established by evaluating the dissolution profile data. The acceptance criterion for a dissolution test is a function of Q, which Is expressed as a percentage of label claim of drug dissolved at a specified time. Typical Q values are in the range of 75%-80% dissolved. Q values in excess of 80% are not generally used because allowance needs to be made for assay and content uniformity ranges."

ix. Following text of a review article titled as "Pharmacokinetics & Drug interactions of Eslicarbazepine acetate":
"Therefore, Eslicarbazepine Acetate is a highly permeable-poorly soluble (BCS class II), drug, whereas Eslicarbazepine is a highly soluble-highly permeable (BCS class I) drug.

- Moreover firm has submitted as under:
  e. Practically we performed BCS class identification tests, material does not belong to BCS Class I.
  f. Due to low solubility of drug dissolution limit Not less than 80% and as per USP General Chapter, <1092> Q-values in the range of 75% to 80%.

Firm has submitted that they have performed dissolution as per FDA dissolution method and the time point is 45 minutes that was published on 27-8-2015 while the reference stated by PEC was published in 2013, so we followed the later one. On the other hand if any product doesn't include in pharmacopoeia then we generally follow USP<1092>, the acceptance criteria for a dissolution is a function of Q which is expressed as a percentage of labeled of drug dissolved a specific time Q value in range of 75% to 80%.

Decision: Registration Board after thorough discussion decided to reject the application "Carelp Tablet 800mg" on the basis of following reasons:

- **Adaptation of dissolution specification NLT 80% of the labeled amount in 45 minutes, while the FDA approved reference product Aptiom tablets have used dissolution specifications NLT 85% in 45 minutes.**
- **Results of dissolution below 85% in 45 minutes at various time intervals.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
475.	M/s Hudson Pharma (Pvt) Ltd., D-93, North Western Industrial Zone Port Qasim Karachi	Brinzoson Eye Drops (Ophthalmic suspension) Each ml contains: Brinzolamide….10mg Brimonidine tartrate….2mg (Anti glaucoma preparation)	Form 5-D Dy No. 12980 06-04-2018 PKR 50,000/- (22-01-2018) (**DUPLICATE**) 5ml: As per SRO	Simbrinza ophthalmic suspension by Novartis **(USFDA** Approved) New section granted on 11-04-2018
	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.# 14615 dated 19-4-2018)**			

STABILITY STUDY DATA	
Drug	Brinzoson Eye Drops (Ophthalmic suspension)
Name of Manufacturer	M/s Hudson Pharma (Pvt) Ltd., D-93, North Western Industrial Zone Port Qasim Karachi

Manufacturer of API	**Brinzolamide:** M/s ICROM S.P.A.,Via Delle Arti, 33–20863 Concorezzo (MB), Italy		
	Brimonidine tartrate: M/s Symed Labs, Limited, Unit-II, Plot No. 25/B, Phase-III. I.D.A., Jeedimetla, Hyderabad, Telangana, India		
API Lot No.	**Brinzolamide:** 001/16M		
	Brimonidine tartrate: 2SU0051016		
Description of Pack (Container closure system)	Eye drops bottle		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3, 6 (Months) Real Time: 0, 1, 3, 6 (Months)		
Batch No.	001	002	003
Batch Size	76 bottles	76 bottles	76 bottles
Manufacturing Date	12-8-2017	12-8-2017	12-8-2017
Date of Initiation	12-8-2017	15-8-2017	16-8-2017
No. of Batches	03		
Date of Submission	**Dy.# 14615 dated 19-4-2018**		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	**Brinzolamide:** Yes
		Brimonidine tartrate: 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.	**Brinzolamide:** Firm has submitted copy of GMP certificate issued by AIFA, Italy issued on 15-02-2017
		Brimonidine tartrate: Firm has submitted copy of GMP certificate issued by DCA, Govt. of Telangana, 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.	**Brinzolamide:** Firm has submitted ADC attested invoice dated 31-5-2017 confirming import of 20gm API along with import of 200mg working standard.
		Brimonidine tartrate: Firm has submitted ADC attested invoice dated 20-6-2017 confirming import of 0.1Kg API.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	No
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules,	Yes

	1978.	

REMARKS OF EVALUATOR

Shortcoming communicated	Response by the firm
The stability data sheets of batch 001, 002 and 003 for 6th months accelerated conditions was signed and approved on 15-02-2018 and 16-2-2018 respectively, while the report of sterility test for the same was signed on 28-02-2018. Justify the development and approval of stability data sheets before the results of sterility test.	Firm has submitted that stability sheets were mainly developed for chemical analysis of product, separate stability sheets were filled with sterility completion. Column for sterility will be left blank till completion of sterility and that will fill after completion of sterility. Now we are putting initial with date on product analysis sheet.
Justify the shifting of retention time of brimonidine from 4.054 at 6th month testing to 5.27 at 3rd month testing and brinzolamide from 7.07 at 6th month testing to 6.01 at 3rd month testing and 5.34 at 1st month testing interval.	Firm has submitted that finished product analytical method is not available in any pharmacopoeia it is in-house method. Analytical method was on development stage and now it is fully developed. With the passage of time column efficiency is affected and retention time depends on column efficiency. On every testing frequency standard peak is comparable to sample peak. Minor difference in retention time may appear due to column efficiency.
Justify the formulation containing brimonidine as tartrate 2mg, since the USFDA approved reference product contains brimonidine tartrate 2mg.	Firm has submitted that they have applied for the same formulation i.e. Brimonidine tartrate 2mg. Firm has submitted revised form 5-D. **The initially submitted form 5-D and master formulation contains brimonidine as tartrate 2mg.**
Justify the finished product specification without benzalkonium chloride assay, osmolality, redispersibility and viscosity since all these tests are included in the specifications of the USFDA approved reference product i.e. Simbrinza ophthalmic suspension.	Firm has submitted that USP has not specified test for preservatives in any ophthalmic formulation. Similarly the standard limits for viscosity and redispersibility are not available therefore we will develop our own limits on commercial batches.
Justify the manufacturing of batches of ophthalmic suspension in August 2017, while the Eye / Ear & Nasal drop (General) section was approved by Central licensing Board vide letter No. F.2-12/2010-Lic (Vol-I) dated 11th April 2018.	Firm has submitted that these stability batches were manufactured in R&D solution filling machine under laminar. Before commercial manufacturing pilot batches will be manufactured and will be kept on stability.

Shortcomings after reply:

Shortcoming communicated	Response by the firm
Justify the initiation and completion of stability studies without analytical method validation, since ICH guidelines Q1A(R2): Stability testing of new drug substances and products specify that "*Analytical procedures should be fully validated and stability indicating*".	Firm has submitted analytical method validation data to justify the initiation of stability studies. The data provided by the firm is of January 2018, while the stability studies were initiated in August 2017.
The initially submitted master formulation dated 19-4-2018 contains brimonidine (as tartrate) 2mg, while in the reply you have mentioned that "we have the same formulation and have submitted Form 5-D with correction". Justification is required since the developed formulation on which stability studies are conducted contains brimonidine (as tartrate) 2mg. Further in case of revision of formulation fee needs to be submitted.	Firm has submitted Form 5-D, composition and manufacturing method of correct formulation. The newly submitted formulation contains different formulation as compared to initially applied formulation.
As per ICH guidelines Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical	Firm has once again submitted that USP has not specified test for preservatives in any ophthalmic formulation. Similarly the standard limits for

Substances and Q1A(R2): Stability testing of new drug substances and products, the testing should cover preservative content and the acceptance criteria should remain part of the specification. Further the guidelines specify, for relatively viscous solutions or suspensions, it may be appropriate to include rheological properties (viscosity/specific gravity) in the specification. Justification is required since these tests are not performed at any testing interval.	viscosity and redispersibility are not available therefore we will develop our own limits on commercial batches. Since after approval this product will be given "Innovator's specification" therefore this product should have been tested for all the tests specified by the innovator product.

- Further firm has used LDPE bottles for eye drops which is a semi permeable container. As per ICH guidelines for drug products packaged in semi-permeable containers the testing conditions are:

Study	Storage conditions
Long Term	30°C ± 2°C/35% RH ± 5% RH
Accelerated	40°C ± 2°C/not more than (NMT) 25% RH

Aqueous-based products packaged in semi-permeable containers should be evaluated for potential water loss in addition to physical, chemical, biological, and microbiological stability.

Decision of 284th meeting of RB:

Registration Board after thorough discussion decided to **reject** the stability data on the basis of following reasons:

- Manufacturing of batches of applied formulation i.e. ophthalmic suspension before the approval of relevant section i.e. Eye / Ear & Nasal drops (General) by Licensing Division, DRAP.

Registration Board further directed the firm to repeat the stability studies as per the recommendations laid down in 278th meeting.

Firm has submitted fresh application for the same product on Form 5-D dated 7th December 2018 along with fee PKR 50,000/- dated 7th December 2018. Firm has submitted same stability study data which was previously rejected.

Decision of 287th meeting of Registration:

Deferred for the opinion of Licensing Division upon following:

"Manufacturing of batches of applied formulation i.e. Cream before the approval of relevant section i.e. Eye / Ear & Nasal drops (General) by Licensing Division, DRAP

Evaluation by PEC:

Firm has submitted that "In lieu of the decision (3-4th January 2019, 287th meeting of registration board) made by the Drug Regulatory Authority of Pakistan (DRAP) on Hudson Pharma's application for registration of Combison and Brinzoson Eye Drops, Hudson Pharma would like to place a humble request for a stability audit. The registration section rejected the stability studies on the aforementioned drugs based on the reason that the stability testing was conducted before the approval of relevant section, i.e. Eye / Ear & Nasal drops. However, we could not find the requirement of relevant section approval prior to stability studies approval in any written DRAP regulations. The Copies of our earlier applications along with supporting documents and Board Decision is annexed herewith for your ready reference and convenience.

Being aggrieved by and dissatisfied with the subject decision, we hereby submit the following grounds for review and reconsideration of the Hon'ble Board member:-

DRAP Laws:-

As far as the DRAP Act and Rules are concerned, we have gone through the relevant provisions and found following relevant to our case:

a. Rule 21 of The Drug (Licensing, Registering and Labelling)Rules, 1976

For the sake of convenience, Rule 21 is reproduced as under:-

21. Licence to manufacture drugs for experimental purposes: (1) If a person intending to manufacture a drug for experimental purposes does not hold a licence to manufacture drugs, he shall before commencing such manufacture, apply in Form 3 for the grant or renewal of a licence to the Central Licensing Board addressed to its Secretary.

As we studied Rule 21 of The Drug Rules 1976, we could not find a requirement for section approval even for the manufacture of drugs for experimental purposes in Form 3.

b. Rule 7 / Form 6 of The Drugs (Import & Export) Rules, 1976

Therefore, the only available option we had was to apply under Rule 7 of The Drugs (Import & Export) Rules, 1976. To obtain Form 6 for import of the APIs for Clinical Trail Examination, Test or Analysis.

Here again, there is no requirement of the Section Approval as per law and it only requires a valid Drug Manufacturing License, which was provided and accordingly the license for import of APIs were allowed for the subject purpose.

International Laws and Practices:

In addition to the above, we also conducted a comprehensive research to know about the international pharma industry practices all over the world. The regulatory requirements for the filing of generic drug applications in the USA and EU envisage that stability testing requirements precede the requirements for section approval. According to the USFDA, the ANDA (Abbreviated New Drug Application) flowchart (Fig 1) depicts that preapproval inspection (in DRAP terminology this would equate to a visit for section approval) is assessed only after chemistry, micro and labelling review is approved. Based on the data that we have studied so far, we can establish that among the major regulatory bodies across the globe, stability studies are done prior to receiving section approval. In fact, in the US and EU, there are large Contract Research Organizations (CROs) that provide outsourcing services for chemistry, biological and stability testing of drugs. Furthermore, in most instances in the EU and US, the stability testing and chemistry review is done at the CRO's facilities which implies that the manufacturing facility or section where the commercial product is manufactured will be different than where the stability testing was conducted.

The explosive proliferation of CRO's and contract manufacturing organizations (CMO's) in China and India is clear evidence that developing market regulators prioritize an efficient approval pathway that encourages innovation and enable new treatments to quickly become available to address the unmet needs of their respective local populations. The new drug approval process that is followed by all large regulatory bodies across the globe has a major advantage of allowing the manufacturer to invest in a facility or section after passing stability studies, biological analysis, chemical analysis, and labelling approval. The main advantage is that it de-risks capital expenditures for drug manufacturers allowing for greater investment and innovation.

Therefore, in light of the data that we have gathered, we wish to extend our invitation to visit of our manufacturing facility at the date and time of your convenience to ensure that the stability results, manufacturing section, and overall facility standards meet your requirements for Combison and Brinzoson"

Decision: Registration Board decided to seek comments of Legal Affairs and Licensing Divisions for following clarification:

- **Can manufacturing of trial batches of a product be carried out in a facility which is not yet approved or licensed by Central Licensing Board?**

b. VERIFICATION OF STABILITY STUDY DATA:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
476.	The Searle company Limited F-319 S.I.T.E Karachi	Ticor 90mg Tablet Each film coated tablet contains: Ticagrelor…..90mg Anticoagulant/ antiplatelet agent Mfg specs	Form 5-D Dy No. 23: 13-3-2017 Rs. 50,000/- 13-03-2017 As Per SRO	Brilinta Tablets by Astra Zaneca (**USFDA** Approved) Last GMP inspection report dated 13-2-2018: Followup, as per the data provided by QALT Division.
	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.# 31206 dated 17-9-2018)**			

STABILITY STUDY DATA	
Drug	Ticor 90mg Tablet
Name of Manufacturer	The Searle company Limited F-319 S.I.T.E Karachi

Manufacturer of API	M/s Alembic Pharmaceuticals Ltd. Vadodara Gujrat.		
API Lot No.	1604000781		
Description of Pack (Container closure system)	Alu-Alu blister pack		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months	Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months)	Real Time: 0, 3, 6 (Months)	
Batch No.	17PD-305	17PD-306	18PD-010
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	December 2017	December 2017	January 2018
Date of Initiation	January 2018	January 2018	January 2018
No. of Batches	03		
Date of Submission	**Dy.# 31206 dated 17-9-2018**		

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.	Firm has submitted GMP certificate of M/s Alembic Pharmaceuticals Ltd. Vadodara Gujrat issued by Food and Drug control administration Gujrat state India on 06-09-2018
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 ADC attested invoice dated 12-01-2017 confirming import of 1.5kg Ticagrelor from M/s Alembic Pharmaceuticals Ltd
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

As per FDA chemistry review, four polymorphic forms of ticagrelor have been identified, out of which one form was used in all preclinical and clinical studies since it does not convert to any other form on storage. Verification of the exact polymorphic form of ticagrelor is required.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Ticor (Ticagrelor) 60mg & 90mg Tablets by M/s The Searle Company Limited, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 23rd January, 2019.
Investigation Date and Time: 11th March, 2019. (Forenoon)
Investigation Site: Factory premises of M/s The Searle Company Limited, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. The Searle Company Limited, Karachi for registration of Ticor (Ticagrelor) 60mg & 90mgTabletsand 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.

"Verification of polymorphic form of Ticagrelor as the FDA chemistry review mentions four polymorphic forms and only one form is not converted into other form on storage"

Composition of Panel:

1. Dr. Rafeeq Alam, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board.
2. Mr. Aslam Shah, 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:

Q.#	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of Ticagrelor API including approval from DRAP?	The firm has imported Ticagrelor raw material 1.5 Kg from M/s Alembic Pharmaceutical Limited, and got approval from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm has implemented proper vendor evaluation system. The rationale for the selection of this manufacturer was availability of GMP certificate from relevant authority, availability of DMF, working standard, stability studies of API.
3.	Do you have documents confirming the import of Ticagrelor reference standard and impurity standards?	The firm has imported working standard along with API consignment. However, impurities testing is done on the basis of RRT.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, and working standards provided by Alembic Pharmaceuticals Limited.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	GMP certificate of API manufacturer issued by Food and Drug Control Administration, Gujrat State, India.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer's method of analysis for API testing.
7.	Do you have stability studies reports on APIs?	The firm has long term (3 years) and accelerated study (6 month) reports for Ticagrelor provided by Alembic Pharmaceutical Limited.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing is as per SIM as Impurity profile has been reported in stability study report of Ticagrelor provided by M/S Alembic Pharmaceutical Limited.
9.	Do you have method for quantifying the impurities in the API?	The firm had API manufacturer method for quantification of impurities in the API and the firm had quantified the impurities on the basis of RRT and impurities are under procurement for further confirmation.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has 0.208 Kg of API Ticagrelor.

11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients i.e. hydroxyl propyl cellolose, Mannitol, Di basic calcium phosphate, sodium starch glycolate, Magnesium stearate.
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 necessary test reports and other record for the excipients used.
14.	Do you have written and authorized protocols for the development of Ticagrelor Tablets Range?	The firm has written and authorized protocols for the development of Ticagrelor Tablets 90mg & 60mg.
15.	Have you performed Drug-excipient compatibility studies?	The firm has used same excipient as used by the innovator (Brilinta / Brilique of AstraZeneca), therefore, compatibility studies were not performed.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies on Ticagrelor Tablets 90mg against Brilique Tablets 90mg having lot no. TERR and Ticagrelor Tablet 60 mg against Brilinta Tablets 60mg having lot no. KAGN, manufactured by AstraZeneca with comparable results.
17.	Do you have product development (R&D) section.	The firm has dedicated product development (R&D) section with requisite manufacturing & analysis facilities.
18.	Do you have necessary equipment available in product development section for development of Ticagrelor Tablets Range?	The firm has necessary equipment available in product development section for development of the Ticagrelor tablets.
19.	Are the equipment in product development section qualified?	The 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 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?	The firm had qualified staff comprising of 24 members in R&D department.
22.	Have you manufactured three stability batches for the stability studies of Ticagrelor Tablets Range required?	The firm has manufactured three stability batches of each strength forstability studies; 1. Ticagrelor Tablets 90mg Batch numbers are 17PD-305, 17PD-306&18PD-010having batch size 2500 tablets each. 2. Ticagrelor Tablets 60mg Batch numbers are 18PD-017, 18PD-018 & 18PD-019 having batch size 2500 tablets each.
23.	Do you have any criteria for fixing the batch size of stability batches?	The firm had informed that their criteria for fixing batch size is based on number of samples required for stability studies for all 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 the method of testing for finished product.
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 Ticagrelor Tablets Range and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Ticagrelor Tablets 90mg & 60mg API and the finished drug.

29.	Do your method of analysis stability indicating?	The firm used stability indicating method for the quantification of any impurities and degradation products in the tablets kept on stability testing.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm. The firm has Water's Alliance 2695 with Empower 3 software.
31.	Can you show Audit trail reports on Ticagrelor Tablets Range testing?	Audit trail on the testing reports is available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches only.
33.	Do you have stability batches kept on stability testing?	The firm has completed accelerated stability testing on three stability batchesof each strength. Currently 12th month real time stability testing has been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in Ticagrelor Tablets Range production and analysis?	The firm has valid calibration status for the equipment used in Ticagrelor Tablet Range for production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Firm has software for monitoring of stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities were GMP compliant.
37.	Any Other query raised by PER Division: Verification of polymorphic form of Ticagrelor as the FDA chemistry review mentions four polymorphic forms and only one form is not converted into other form on storage	The firm has procured polymorphic form II, the same has been confirmed by comparing the XRD results of manufacturer and a patent available WO2013/079589 A1, The API manufacturer has provided declaration of polymorphic form II and they have also obtained market authorization from USFDA conditionally with expiration of patent, which also shows the polymorphic form II is accepted by USFDA.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Ticor 60mg & 90mg Tablets (Ticagrelor) is verifiable to satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are compliant and are suited for the manufacturing of Ticor 60mg & 90mg Tablets.

Recommendations:

1. The firm may kindly be granted necessary registration of Ticor 60mg & 90mg tablets.
2. Since Ticagrelor falls in BCS Class IV (Low solubility and low permeability), therefore requires Bioequivalence Studies. Therefore, post-registration bioequivalence studies are also recommended.

Note: The firm has submitted written commitment vide letter No. NIL dated 11th March, 2019 for bioequivalence studies on Ticor tablets

Decision: Registration Board decided to approve registration of "Ticor (Ticagrelor) 60mg & Ticor (Ticagrelor)90mg Tablets with Innovator's specifications by M/s The Searle Company 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.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
477.	M/s Global Pharmaceuticals (Pvt) Ltd., Plot # 204-205, Industrial	Velcure Plus Tablet Each film coated tablet contains: Sofosbuvir…..400mg	Form 5-D Dy No. 15519 26-04-2018 PKR 50,000/-	Epclusa Tablets by Gilead Sciences (**USFDA** Approved)

	Triangle Kahuta Road, Islamabad.	Velpatasvir co-povidone eq. to velpatasvir….100mg (Anti-viral)	(24-7-2018) 28's: As per SRO	
	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.# 15519 dated 26-4-2018)**			

STABILITY STUDY DATA			
Drug	Velcure Plus Tablet		
Name of Manufacturer	M/s Global Pharmaceuticals (Pvt) Ltd., Plot # 204-205, Industrial Triangle Kahuta Road, Islamabad.		
Manufacturer of API	**Sofosbuvir:**M/s Suli Pharmaceutical Technology Jiangyin Co Ltd., No. 2 Runhua Road, Harbour Economic Development District, Jiangyin, Jiangsu Province China		
	Velpatasvir:M/s Nantong Chanyoo Pharmatech Co. Ltd., No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province.		
API Lot No.	**Sofosbuvir:**SLZY059-Form6-17060101		
	Velpatasvir:201703002		
Description of Pack (Container closure system)	HDPE Bottles with child resistant closure		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks) Real Time: 0, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26 (Weeks)		
Batch No.	T-035(Q)	T-036(Q)	T-037(Q)
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	04-08-2017	04-08-2017	04-08-2017
No. of Batches	03		
Date of Submission	**Dy.# 15519 dated 26-4-2018**		

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.	**Sofosbuvir:** Firm has submitted GMP certificate of M/s Suli Pharmaceutical Technology issued by Jiangsu Changzhou Drug Administration
		Velpatasvir: Firm has submitted copy of GMP certificate issued by Nantong Food and Drug Administration. Copy of "Certificate of GMP Compliance of a Manufacturer" issued by "Agency for medicinal products and medical devices of the Republic of Solvenia" for the M/s Nantong Chanyoo Pharmatech Co.Ltd verified from following website link of European Inspections database, when visited on 18-10-32016: http://eudragmdp.ema.europa.eu/inspections/gmpc/s

		earchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=28517 has been verified.
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:** Firm has submitted ADC attested invoice on 19-6-2017 confirming import of 100Kg sofosbuvir. The ADC attested invoice is for already registered Cure-C tablet.
		Velpatasvir: Firm has submitted ADC attested invoice dated 21-4-2017 confirming import of 1 Kg velpatasvir copovidone.
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

Observations	Reply by the firm
Justify the submitted specification of dissolution test under the "finished product specification" specify the limit as NLT 75% (Q+5%), while as per "Guidance for Industry, Dissolution testing of Immediate Release Solid Oral Dosage Forms" issued by USFDA, a single-point dissolution test specification of NLT 85% (Q=80%) in 60 minutes or less is sufficient as a routine quality control test for batch-to-batch uniformity."	The firm has replied that "we have not found any specific guidelines in this regard so we adopted this value i.e. NLT 75% (Q+5%) at 30 minutes. We can change our specification limits to NLT 80% on your suggestion. Firm has further stated that DRAP has already approved same combination with 80% dissolution for some companies.
GMP certificate of the API manufacturer issued by concerned regulatory authority of China, since the submitted copy of GMP certificate is issued by district regulatory authority, while as per Drug Administration Law of the People's Republic of China, Chapter-I General Provisions; Article 5 as discussed in 274th meeting of Registration Board "The drug regulatory department of the people's government at or above the provincial level shall organize inspections of drug manufacturers in accordance with the Good Manufacturing Practice for Pharmaceutical Products (GMP) and the measures and schedule for implementing the GMP formulated by the drug regulatory department under the State Council, and issue a certificate to the manufacturer that complies with the GMP"	Firm has submitted that the supplier of sofosbuvir i.e. M/s Suli Pharmaceutical Technology Jiangyin Co Ltd is our DRAP approved source in case of "Cure-C Tablet". That's why we have used the same source in this product as well. Firm in its later reply submitted that their API was manufactured by Jiangsu Yongda instead of Suli Pharma which is only a supplier in this case. The response of the firm was sent to AD (I&E) Islamabad office for verification of the stance of the firm. AD (I&E) office vide their letter No. F.4-15/2018-I&E/QA&LT dated 15th November 2018 submitted the copies of Form 3, Form 5 and Form 7. Form 5 (License to Import drugs) confirm that the material is manufactured by Suli Pharma China, While Form 3 and Form 7 confirms that the manufacturer is Jiangsu Yongda Pharma, China.

Report on Inspection of Authenticity / Genuineness of data submitted for registration of Velcure Plus (Velpatasvir…..100 mg + Sofosbuvir……400 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: 08th (Morning) and 27th February 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 Velcure Plus (Velpatasvir…..100 mg + Sofosbuvir……400 mg) Tablets with following composition:

Velcure Plus Tablets
Each film coated tablet contains:-
Sofosbuvir……..400 mg
Velpatasvir copovidone eq. to Velpatasvir……...100 mg

Chairman Registration Board constituted following 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 findings/verification inspection are 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?	**Sofosbuvir** Invoice Number: **17SLZY023** ADC attestation date: **19.06.2017** Exporter: M/s Suli Pharmaceuticals Technology Jiangyin Co. LTD. No.2 Runhua Raod Harbour Economic Development District, Jiangyin Jiangsu Province, China 214444. Manufacturer: M/s Jiangsu Yongda Pharmaceutical Co. Ltd. No.05 Guangqu Road, New North Area, Changzhou, Jiangsu, China, 213001. Batch No. SLZY059 Manufacturing Date: 29.04.2017 Retest Date: 28.04.2018 Quantity: 100 kg (The quantity was already in use in manufacturing of commercial batches of registered product Cure-C (Sofosbuvir) 400 mg Tablet). **Velpatasvir Copovidone** Invoice Number: **CY117070** ADC attestation date: **21-04-2017** Exporter: M/s Changzhou Pharmaceutical Factory., 518 Laodong, East road, Changzhou Jiangsu Province, China Manufacturer: M/s Nantong Chanyoo Pharmatect Co. Ltd. China No. 2, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal

<table>
<tr><td></td><td></td><td>Economic Development Zone, Nantong, Jiangsu Province 226407, P.R. China
Batch No. 201703002
Mfg. Date: 16-03-2017
Exp. Date: 15-03-2018
Quantity: 01kg</td></tr>
<tr><td>2.</td><td>What was the rationale behind selecting the particular manufacturer of API?</td><td>Sofosbuvir
The firm has submitted that M/s Jiangsu Yongda Pharmaceutical Co. Ltd. is their regular supplier and has Valid GMP; Client List of API manufacture contains International and Local clients, Stability Data (Accelerated and Real Time).
Velpatasvir Copovidone
The firm has submitted a comparison sheet showing different parameters to compare among 3 different sources API. M/S Nantong was selected on the basis of Valid GMP, good impurity profile, previous history of Antiviral manufacturing and good Client List of API manufacture contains International and Local client. The firm has already used the “Daclatasvir” from the same suppliers.
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.</td></tr>
<tr><td>3.</td><td>Do you have documents confirming the import of Sofosbuvir and velpatasvir copovidone reference standard and impurity standards?</td><td>The firm imported following reference standards:
Sofosbuvir:
<table>
<tr><th>Name of product</th><th>Source</th><th>Batch No.</th><th>Quantity</th><th>Invoice No.</th><th>Mfg. date</th><th>Exp. date</th></tr>
<tr><td>Impurity Standard SFBA-1</td><td>M/s Suli Pharmaceutical Technology via Nimbus Chemtech</td><td>SLZY059B-1701001</td><td>1 gm</td><td>-</td><td>24.05.17</td><td>24.05.18</td></tr>
</table>
The firm has developed tertiary working standard of Sofosbuvir from secondary standards B.No.WS59-141001-Form6 provided by the Manufacturer/source for Sofosbuvir.
Velpatasvir Copovidone:
Firm has imported Working Standard and impurities as per details below:
<table>
<tr><th>Name of product</th><th>Source</th><th>Batch No.</th><th>Quantity</th><th>Invoice No.</th><th>Mfg. date</th><th>Exp. date</th></tr>
<tr><td>Velpatasvir Working Standard</td><td>M/s Nantong Chanyoo Pharmatect Co. Ltd. China via Changzhou Pharmaceutical, Factory, China.</td><td>WS2016100 01</td><td>1 gm</td><td>CY117070A</td><td>15.10.16</td><td>14.1017</td></tr>
<tr><td>Dihydrogen of VLP</td><td>As above</td><td>WVLP0161101</td><td>100 mg</td><td>As above</td><td>10.11.16</td><td>09.1117</td></tr>
<tr><td>VLP-10</td><td>As above</td><td>WVLP04161201</td><td>100 mg</td><td>As above</td><td>05.12.16</td><td>04.1217</td></tr>
<tr><td>VLP-11</td><td>As above</td><td>WVLP03161201</td><td>100 mg</td><td>As above</td><td>10.12.16</td><td>09.1217</td></tr>
<tr><td>VLP-C</td><td>As above</td><td>WVLP02161201</td><td>100 mg</td><td>As above</td><td>17.12.16</td><td>16.1217</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>The firm again imported the following reference standards on 12.10.2017 as per details below:
<table>
<tr><th>Name of product</th><th>Source</th><th>Batch No.</th><th>Quantity</th><th>Invoice No.</th><th>Mfg. date</th><th>Exp. date</th></tr>
<tr><td>Velpatasvir Working Standard</td><td>M/s Nantong Chanyoo Pharmatect Co. Ltd. China via Neon Chemicals</td><td>WS2017100 01</td><td>1 gm</td><td>-</td><td>05.10.17</td><td>04.10.18</td></tr>
<tr><td>Dihydrogen of VLP</td><td>As above</td><td>20170 7001</td><td>30 mg</td><td>As above</td><td>10.06.17</td><td>09.06.18</td></tr>
<tr><td>VLP-10</td><td>As above</td><td>20170 7001</td><td>30 mg</td><td>As above</td><td>04.07.17</td><td>03.07.18</td></tr>
<tr><td>VLP-11</td><td>As above</td><td>20170 7001</td><td>30 mg</td><td>As above</td><td>07.07.17</td><td>06.07.18</td></tr>
<tr><td>VLP-C</td><td>As above</td><td>20170 7001</td><td>30 mg</td><td>As above</td><td>06.07.17</td><td>05.07.18</td></tr>
</table>
* M/s Nantong Chanyoo Pharmatect Co. Ltd. China No. 2, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Econimic Development Zone, Nantong, Jiangsu Province 226407, P.R. China.</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 drugs (APIs)/materials of source as mentioned below:
Sofosbuvir
✓ Sofosubuvir (API) B.No.SLZY059-Form6-17060101
✓ Sofosubuvir reference standard B.No.WS59-141001-Form6
✓ Impurity Standard SFBA-1 from the Source/Manufacturer (Batch No. SLZY059B-1701001).
Velpatasvir Copovidone
✓ Velpatasvir Copovidone (API)
✓ Velpatasvir Working Standard from the Source/Manufacturer
✓ Impurity Standard Dihydrogen of VLP
✓ Impurity Standard VLP-10
✓ Impurity Standard VLP-11
✓ Impurity Standard VLP-C</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>Sofosbuvir
The firm has submitted copy of GMP certificate No: JS20150406 in the name of Manufacturer that is “M/s Jiangsu Yongda Pharmaceutical Co. Ltd. No.05 Gangqu Road, chunjiang town, New North Area, Changzhou, Jiangsu, China,” of <u>Sofosbuvir</u> by the Certifying Authority of “Jiangsu Food & Drugs Administration, China.”
Issued on: 30-03-2015
Valid upto: 29-03-2020
<u>Velpatasvir Copovidone</u>
The firm has submitted copy of GMP certificate No: 2017006 in the name of Manufacturer that is “M/s Nantong Chanyoo Pharmatech Co. Ltd. No. 2, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Econimic Development Zone, Nantong, Jiangsu Province 226407, P.R. China for source of <u>Velpatasvir Copovidone</u> by the Certifying Authority of “Nantong Food & Drugs Administration (China)”
Issued on: 08-09-2017
Valid upto: 07-09-2020</td></tr>
<tr><td>6.</td><td>Do you use API manufacturer method of testing for testing API?</td><td>The firm has used method of testing for testing API Sofosbuvir & Velpatasvir Copovidone provided from their respective manufacturers.</td></tr>
</table>

<table>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>Sofosbuvir:
Firm has submitted data of accelerated stability studies data of three batches SLZY059-150102-Form 6 (Mfg.: 08th Feb, 2015), SLZY059-150401-Form 6 (Mfg: 04th Apr, 2015), & SLZY059-150501-Form 6 (Mfg:01st June, 2015), up to 6 months and for real time data up to 36 month, conducted by the API manufacturer “M/s Suli Pharmaceuticals Technology Jiangyin Co. LTD. No.2 Runhua Raod Harbour Economic Development District, Jiangyin Jiangsu Province, China 214444 for API namely Sofosbuvir .The data submitted by the API manufacturers lies within the limits for the assay, water & impurities.
<u>Velpatasvir Copovidone:</u>
Firm has submitted data of three batches 201611001 (Mfg.: 07th Nov, 2016), 201611002 (Mfg.: 15th Nov, 2016), & 201611003 (Mfg.: 23rd Nov, 2016), for accelerated stability studies up to 6 months and for real time data up to 24 month, conducted by the API manufacturer “M/s Nantong Chanyoo Pharmatech Co. Ltd. China No. 2, Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, P.R. China for API namely <u>Velpatasvir Copovidone.</u>The data submitted by the API manufacturers lies within the limits for the Assay water & impurities.</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 studies of the API the determination of impurities, degradation products (as per definition of SIM).</td></tr>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm stated that they have used the vendor provided methods for quantifying the impurities in the API Sofosubvir and velpatasvir.</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 (approx.)</th><th>Consumption Details</th><th>Consumed amount (approx.)</th><th>Remaining amount (approx.)</th></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Velpatasvir copovidone</td><td rowspan="2">201703002</td><td rowspan="2">1kg</td><td>Raw material Testing
Pre formulation Trial, (T-034(Q))</td><td>10g
90g</td><td>990gm
900gm</td></tr>
<tr><td>03 Stability Batches, T-035(Q), T-036(Q), T-037(Q)</td><td>900g</td><td>Nil</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2">Sofosbuvir</td><td rowspan="2">17060101</td><td rowspan="2">2kg</td><td>Pre-formulation Trial, T-034(Q)</td><td>180g</td><td>1820gm</td></tr>
<tr><td>Three Stability Batches,T-035(Q), T-036(Q),T-037(Q)</td><td>1800g</td><td>20gm</td></tr>
<tr><td>3</td><td>Velpatasvir Copovidon (Working. Standard)</td><td>WS201610001</td><td>1 g</td><td>Raw material Testing to 8th week of stability testing</td><td>135mg</td><td>865mg</td></tr>
<tr><td>4</td><td>Dihydrogen- VLP impurities</td><td>WVLP05-161101</td><td>100mg</td><td>Expired</td><td>----</td><td>100mg</td></tr>
<tr><td>5</td><td>VLP -11 impurities</td><td>WVLP03-161201</td><td>100mg</td><td>Expired</td><td>-----</td><td>100mg</td></tr>
<tr><td>6</td><td>VLP-10 impurities</td><td>WVLP04-161201</td><td>100mg</td><td>Expired</td><td>-----</td><td>100mg</td></tr>
<tr><td>7</td><td>VLP-C impurities</td><td>WVLP02-161201</td><td>100mg</td><td>Expired</td><td>-----</td><td>100mg</td></tr>
<tr><td>8</td><td>Velpatasvir Copovidon (Working. Standard)</td><td>WS201710001</td><td>1 g</td><td>Stability Batches</td><td>90mg</td><td>910mg</td></tr>
<tr><td>9</td><td>Dihydrogen- VLP impurities</td><td>201707001</td><td>30mg</td><td>Finished Product</td><td>30mg</td><td>Nil</td></tr>
<tr><td>10</td><td>VLP -11 impurities</td><td>201707001</td><td>30mg</td><td>Finished Product</td><td>30mg</td><td>Nil</td></tr>
<tr><td>11</td><td>VLP-10 impurities</td><td>201707001</td><td>30mg</td><td>Finished Product</td><td>30mg</td><td>Nil</td></tr>
<tr><td>12</td><td>VLP-C impurities</td><td>201707001</td><td>30mg</td><td>Finished Product</td><td>30mg</td><td>Nil</td></tr>
<tr><td>13</td><td>SFBA1 (sofosbuvir)</td><td>1701001</td><td>200mg</td><td>Finished Product</td><td>100mg</td><td>Approx: 100mg</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm has used pharmaceutical grade excipients as indicated from the COAs submitted by firm.</td></tr>
</table>

<table>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm purchased the excipients used in the applied formulation from local suppliers as per details below:
<table>
<tr><th>S.No</th><th>ITEM NAME</th><th>PHARMACOLGOCAL NATURE</th></tr>
<tr><td>1</td><td>Avicel 102</td><td>Excipient</td></tr>
<tr><td>2</td><td>Crosscarmellose Sodium</td><td>Excipient</td></tr>
<tr><td>3</td><td>Magnesium Stearate</td><td>Excipient</td></tr>
<tr><td>4</td><td>Tabcoat white</td><td>Excipient</td></tr>
<tr><td>5</td><td>Tabcoat orange</td><td>Excipient</td></tr>
</table></td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>The firm has performed tests on above mentioned excipients and hence 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 Velcure Plus tablets 400/100mg (<u>Velpatasvir + Sofosbuvir)</u>?</td><td>The firm has written and authorized protocols for the development of Velcure Plus Tablet. But submitted documented was not in accordance with ICH Q-8 which actually pertains to Pharmaceutical Development. The firm was advised to improve the submitted protocol in the light of said document.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>The firm has not performed Drug-Excipients compatibility studies as their formulation (API & Excipients) is similar/comparable to that of the EPCLUSA Tablet approved by EMA.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative dissolution studies against the EPCLUSA Tablet (B# YPPGD1) approved by EMA. However, the studies seem improvement for example the firm has used 6 units for both test and reference products instead of 12 as recommended in USFDA Guidance for Industry: Dissolution testing of immediate release solid oral dosage form.</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>The firm possesses an approved Research & Development (R&D) and Validation Department for product development studies.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Velcure Plus tablets?</td><td>The firm has following necessary equipment in R & D section though for the development of Velcure Plus Tablet.
<table>
<tr><th colspan="8">Research & Development</th></tr>
<tr><th>Machine /Equipment Name</th><th>Machine ID #</th><th>Model/Make</th><th>Capacity</th><th>Location</th><th>Qualification No.</th><th>Calibration Date</th><th>Calibration Due Date</th></tr>
<tr><td>Multifunctional Experimental Machine</td><td>GL/R&D/698</td><td>SD-1/STC-China</td><td>1.00kg</td><td>R&D</td><td>IQ-234/08-10
OQ-235/08-10
PQ-236/08-10</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Manual Capsule Filling Machine</td><td>GL/R&D/668</td><td>Manual/Pakistan</td><td>600cap/Hr.</td><td>R&D</td><td>IQ-237/03-13
OQ-238/03-13
PQ-239/03-13</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Magnetic Stirrer</td><td>GL/R&D/738</td><td>78HW1/China</td><td>--</td><td>R&D</td><td>IQ-317/09-15
OQ-318/09-15</td><td>N/A</td><td>N/A</td></tr>
<tr><td>Disintegration Apparatus</td><td>GL/R&D/755</td><td>BJ-2/Guoming-china</td><td>Double Basket</td><td>R&D</td><td>IQ-338/02-16
OQ-339/03-16</td><td>20-08-2017</td><td>20-08-2018</td></tr>
<tr><td>Precision Balance</td><td>GL/R&D/678</td><td>TX-300/Akira-Japan</td><td>300gm</td><td>R&D</td><td>IQ-249/03-15
OQ-250/03-15</td><td>20-08-2017</td><td>20-08-2018</td></tr>
<tr><td>Weighing Balance</td><td>GL/R&D/001</td><td>SBZ/Pakistan</td><td>10.0 Kg</td><td>R&D</td><td>IQ-523/03-17
OQ-524/03-17</td><td>20-08-2017</td><td>20-08-2018</td></tr>
<tr><td>Stability Chamber (Accelerated)</td><td>GL/R&D/655</td><td>I-01/Instrumend-Pakistan</td><td>100 Packs</td><td>R&D</td><td>IQ-244/03-13
OQ-245/03-13
PQ-246/03-13</td><td>18-08-2017</td><td>18-08-2018</td></tr>
<tr><td>Stability Chamber(Real Time)</td><td>GL/R&D/034</td><td>R1-201/Raxell-Pakistan</td><td>200 Packs</td><td>R&D</td><td>IQ-110/05-08
OQ-111/05-08
PQ-112/05-18</td><td>19-08-2017</td><td>19-08-2018</td></tr>
<tr><td>Dissolution Apparatus</td><td>GL/R&D/777</td><td>RC-8/Guoming-China</td><td>8 Vessels</td><td>R&D</td><td>IQ-594/08-17
OQ-595/08-17</td><td>20-08-2017</td><td>20-08-2018</td></tr>
<tr><td>HPLC</td><td>GL/R&D/753</td><td>Hitachi</td><td>--</td><td>R&D</td><td>External</td><td>28-07-2017</td><td>28-07-2018</td></tr>
<tr><td>HPLC</td><td>GL/R&D/819</td><td>Hitachi</td><td>--</td><td>R&D</td><td>External</td><td>13-08-2018</td><td>13-08-2019</td></tr>
<tr><td>Stability Chamber(Real Time)</td><td>GL/R&D/035</td><td>Thermolab / India</td><td>-</td><td>R&D</td><td>IQ-110/05-08
OQ-111/05-08
PQ-356/04-16</td><td>17-08-2017</td><td>17-08-2018</td></tr>
<tr><td>Stability Chamber(Real Time)</td><td>GL/R&D/768</td><td>SC750L / Instrumends</td><td>-</td><td>R&D</td><td>-</td><td>05-09-2018</td><td>05-09-2019</td></tr>
</table></td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The equipment used in production and analysis of trial batches are qualified as per details mentioned in reply of above question # 18.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance/calibration/re-qualification program for the</td><td>The firm has calibration program for the equipment used in production and QC as per details mentioned in reply of question 18.</td></tr>
</table>

<table>
<tr><td></td><td>equipment used in PD section?</td><td></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 appointed a team of following technical personnel:
<table>
<tr><th>Sr. #.</th><th>Employee Name</th><th>Designation</th><th>Qualification</th><th>Experience</th></tr>
<tr><td>1.</td><td>Mr. Muhammad Jamil</td><td>Manager R&D</td><td>M. Sc. Analytical Chemistry</td><td>17 years</td></tr>
<tr><td>2.</td><td>Dr. Tanseer Abbas</td><td>Executive</td><td>Pharm -D</td><td>06 Years</td></tr>
<tr><td>3.</td><td>Atif Ali</td><td>Executive</td><td>M. Sc. Chemistry</td><td>5 years</td></tr>
<tr><td>4.</td><td>Dr. Anas Ullah</td><td>Senior analyst</td><td>Pharm D</td><td>4.5 years</td></tr>
<tr><td>5.</td><td>Muhammad Zubair</td><td>Analyst</td><td>M. Sc. Chemistry</td><td>1.5 Years</td></tr>
<tr><td>6.</td><td>Miss Kainat Zahra</td><td>Pharmacist</td><td>Pharm D</td><td>06 month</td></tr>
</table></td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Velcue Plus tablets?</td><td>The firm has manufactured following three stability batches for the stability studies of Velcure Plus Tablet:
<table>
<tr><th>S. No.</th><th>Stability Batchs</th><th>Batch Sizes</th></tr>
<tr><td>a.</td><td>T-035Q</td><td>1500 tablets</td></tr>
<tr><td>b.</td><td>T-036Q</td><td>1500 tablets</td></tr>
<tr><td>c.</td><td>T-037Q</td><td>1500 tablets</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>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#</th><th>Batch Sizes</th><th>Tablets for real time studies</th><th>Tablets for accelerated studies</th><th>Total packs per batch required</th></tr>
<tr><td>a</td><td>1500 tablets</td><td>448 Tablets
OR
16 Packs</td><td>336 Tablets
OR
12 Packs</td><td>784 Tablets
OR
28 Packs</td></tr>
</table>
Batch size = 1500 Tablets, Pack Size 28’S</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. Starting from Raw Material manufacturing order sheet assuring the traceability of manufacturing and analysis of all the three stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has controlled protocol for 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.</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 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:
i. Specificity
ii. Precision
a. Repeatability
b. Intermediate Precision
iii. Accuracy
iv. Linearity
v. Robustness
vi. System Suitability
vii. Limit of Quantification/Detection
viii. Range
Remarks: The firm has started initial testing of samples placed on stability on 04.08.2017 while the validation of testing method performed on 17.07.2017.</td></tr>
</table>

<table>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has not conducted method transfer studies. According to the firm since their analytical method is developed by them hence no method transfer studies are required.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualifications of equipment /instruments being used in the test and analysis of APIs and the finished drug</td><td>The firm showed documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished drug.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm’s method of testing is stability indicating for stability testing of their finished product, the data sheet submitted by firm verifies the testing of impurity on samples kept on stability studies. The firm has conducted impurity testing at one time at 6th month time point it was discussed to conduct the impurity testing at initial and end time point (i.e., at 0 and 6) to get an exact verification of impurity profiling/level.</td></tr>
<tr><td>30.</td><td>Do your HPLC software is 21CFR compliant?</td><td>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 Velcure Plus 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 available and verifiable.</td></tr>
<tr><td>31.</td><td>Can you show Audit Trail reports on Velcure Plus tablets testing?</td><td>A complete trail of such testing was found available and verifiable from log books, analytical test reports and software of HPLC as well.</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 as per following details:
<table>
<tr><th>S#</th><th>Batch No.</th><th>Total Packs</th><th>Samples for accelerated studies</th><th>Samples for Real Time studies</th><th>Remaining Packs</th></tr>
<tr><td>1</td><td>T-035Q</td><td>50</td><td>12 Packs</td><td>16 Packs</td><td>22</td></tr>
<tr><td>2</td><td>T-036Q</td><td>49</td><td>12 Packs</td><td>16 Packs</td><td>21</td></tr>
<tr><td>3</td><td>T-037Q</td><td>50</td><td>12 Packs</td><td>16 Packs</td><td>22</td></tr>
</table></td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm has completed the accelerated stability testing on the three stability batches of Velcure Plus Tablet. Also the firm has completed the real time stability testing up to 18 months on all three batches.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipments used in production in analysis?</td><td>The firm has valid calibration status for the equipment used in Velcure Plus Tablet production and analysis as per record available during onsite visit.</td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>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 date-wise data for every next hour of temperature and humidity conditions of stability chambers used for accelerated and real time studies.</td></tr>
<tr><td>36.</td><td>Do related manufacturing</td><td>The related manufacturing area, equipment, personnel and utilities are rated</td></tr>
</table>

	area, equipment, personnel and utilities be rated as GMP compliant?	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 Velcure Plus tablets is verifiable to a satisfactory level.

2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suitable for the manufacturing of Velcure Plus tablets, therefore, the panel recommends the registration of Velcure Plus tablets in the name of the manufacturer.

Decision: Registration Board decided to approve registration of "Velcure Plus Tablets" with Innovator's specifications by M/s Global Pharmaceuticals (Pvt) Ltd., Plot # 204-205, Industrial Triangle Kahuta Road, Islamabad. Manufacturer will place first three production batches 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 GMP Inspection Report Date & Remarks
478.	M/s. TITLIS Pharma 528-A Sundar Industrial Estate, Lahore	Delanso Capsule 30mg Each capsule contains: Enteric coated pellets of Dexlansoprazole …30 mg (Proton pump inhibitor)	Form 5-D Dy. No. 196 15-09-2014 PKR 50,000/- 10's: As per brand leader	DEXILANT 30mg Delayed release Capsule USFDA approved
		Delanso Capsule 60mg Each capsule contains: Enteric coated pellets of Dexlansoprazole …60 mg (Proton pump inhibitor)	Form 5-D Dy. No. 201 15-09-2014 PKR 50,000/- 10's: As per brand leader	DEXILANT 60mg Delayed release Capsule USFDA approved

Remarks of Evaluator:

M/s Titlis Pharma had initially submitted stability data for above applied formulations by using pellets from M/s. Lee Pharma Ltd. India, but in 276th meeting of Registration Board the representative of M/s. Titlis Pharma, Lahore, appeared and apprised the Board that the pellets used in stability batches do not possess dual delayed release profile so they will perform and submit new stability studies with different source of pellets. Hence Board acceded with request of M/s Titlis Pharma and directed to submit new stability data using pellets of dual delayed release profile as per reference product.

Now recently firm had submitted new stability data by using pellets from M/s Vision Pharmaceuticals, Islamabad, which was evaluated and proceeded for the onsite inspection.

Report on Inspection of Authenticity / Genuineness of data submitted for registration of Delanso Capsules 30mg & Delanso capsules 60mg by M/s Titlis Pharmaceuticals Lahore.

Inspection Date and Time: 02nd May, 2019
Inspection Site: M/s. Titlis Pharma, 528-A, Sunder Industrial Estate, Lahore.

Composition of Panel:

1. Mr. Shafiq-ur-Rehman (Director DTL, Lahore)
2. Miss Ufaq Tanveer Butt (FID, DRAP, Lahore)
3. Miss Maham Misbah. (Assistant Director, DRAP, Lahore)

Product: DELANSO 30mg & 60mg Capsules
Firm: M/s Titlis Pharmaceuticals Lahore

Q.#	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import API including approval from DRAP?	The firm has not imported the API. Rather, the firm has procured 1 kg Dexlansoprazole DDR pellets locally from M/s Vision Pharmaceuticals, Islamabad, having Batch number DLP240T vide Invoice No.VP0001 dated May 03, 2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	Previously, firm had conducted stability studies using pellets from another source (M/s. Lee Pharma India). During personal hearing, M/s Titlis Pharma had apprised the Drug Registration Board in its 276th meeting that the pellets used in stability batches did not possess dual delayed release profile. The board had directed M/s Titlis Pharma to submit new stability data using pellets of dual delayed release profile as per reference product (Dexilant capsules of M/s Takeda Pharma). Selection of the manufacturer is also based upon its GMP,ISO 9001: 2015, 17025, 14001, PNAC Certification and already Approved DRAP source. Eight companies have obtained registration approval with source Vision Pharmaceuticals Islamabad.
3.	Do you have documents confirming the import of API reference standard and impurity standards?	No reference standard and impurity standards were available. But the Firm had procured working standard of API from Vision Pharmaceuticals Islamabad.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The Firm had certificate of analysis of API and Working standard of API.
5.	Do you have GMP certificate of APIs manufacturer issued by regulatory authority of country of origin?	Yes, The Firm had cGMP Certificate of API's manufacturer (M/s Vision Pharmaceuticals, Islamabad) issued by Drug Regulatory Authority of Pakistan.
6.	Do you use APIs manufacturer method of testing for testing APIs?	Yes, The Firm is using manufacturer method for testing of Dexlanoprazole DDR pellets.
7.	Do you have stability studies reports on API?	Yes, Thefirm has six month accelerated and 36 months real time stability studies report of API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes, The stability testing has been performed as per SIM method and degradation products have been quantified. Degradation Products are Sulphones & Sulphides. Total Impurity: NMT 2% (Total Impurity Identified 1.06%)
9.	Do you have method for quantifying the impurities in the API?	Yes, The Firm had the method for quantifying the impurities in the API by normalization method.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes, The Firm had remaining quantities of API and working standard of API.
11.	Have you used pharmaceutical grade excipients?	Not Applicable; Only encapsulation of ready to fill pellets is being performed.
12.	Do you have documents confirming the import of the used excipient?	Not Applicable; Only encapsulation of ready to fill pellets has been performed.
13.	Do you have test reports and other records on the excipients used?	Not Applicable; Only encapsulation of ready to fill pellets has been performed.
14.	Do you have written and authorized protocols for the development of Dexlansoprazole DDR 30mg Capsules?	Yes, The Firm had written and authorized protocols for the development of DELANSO (Dexlansoprazole) Capsules 30mg and 60mg.
15.	Have you performed Drug-excipients compatibility studies?	Not Applicable; Only encapsulation of ready to fill pellets has been performed.
16.	Have you performed comparative dissolution	Yes, The Firm had performed comparative dissolution

<table>
<tr><td></td><td>studies?</td><td>studies with DEXILANT Capsules 30mg and 60mg manufactured by M/s Tekeda Pharmaceuticals Limited (Japan). However, the firm used six vessel dissolution apparatus (Type II, Model of DS-2013 and Make by Curio Pakistan).
The firm was advised to purchase twelve vessel dissolution apparatus for performing comparative dissolution studies.
The firm was testing Dual Delay Release Profile by testing the dissolution of the pellets at pH 5.5 and at pH 7</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>Yes, The firm had product development (R&D) section for product development,manufacturing& testing facilities for trial batches.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Dexlansoprazole DDR 30mg Capsules?</td><td>The firm used automatic capsule filling machine of production area (Model: NJP 800) for manufacturing of trial batches. Dedsuster was built in the machine. The Capsule Polisher (Model HJP-C- Model 150) was available for capsule polishing. Firm was advised to purchase metal detector.</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>Yes, All the equipments used in production &testing of Delanso 30mg 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>Yes, The firm had proper maintenance & calibration Plan for the equipment used in Product Development. (Plan Attached)</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>Yes, The firm had qualified staff with suitable knowledge and training in product development. (Organogram Attached)</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Dexlansoprazole DDR 30mg capsules as required?</td><td>The firm have manufactured three stability batches for the stability studies with following details:
<table>
<tr><th>Batch #</th><th>Mfg date</th><th>Batch size</th></tr>
<tr><td colspan="3">Delanso 30mg Capsules</td></tr>
<tr><td>T-050</td><td>MAY – 2018</td><td>500 Capsules</td></tr>
<tr><td>T-051</td><td>MAY – 2018</td><td>500 Capsules</td></tr>
<tr><td>T-052</td><td>MAY – 2018</td><td>500 Capsules</td></tr>
</table>
<table>
<tr><th>Batch #</th><th>Mfg date</th><th>Batch size</th></tr>
<tr><td colspan="3">Delanso 60mg Capsules</td></tr>
<tr><td>T-053</td><td>MAY – 2018</td><td>500 Capsules</td></tr>
<tr><td>T-054</td><td>MAY – 2018</td><td>500 Capsules</td></tr>
<tr><td>T-055</td><td>MAY – 2018</td><td>500 Capsules</td></tr>
</table>
The capsules are packed in blisters Alu/Alu foil with pack size of 2×7's.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches are based upon the number of Capsules per testing and testing frequencies.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>Yes, The firm had complete record of production of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Yes, The firm had protocols for stability 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 had validated method for the testing of Delanso 30mg and 60mg Capsules.</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 given by any other lab?</td><td>The firm is using manufacturer method of testing, and has validated the method of testing.</td></tr>
</table>

<table>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?</td><td>Yes, The firm had documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug.</td></tr>
<tr><td>29.</td><td>Does your method of analysis stability indicating?</td><td>Yes, The method of analysis is stability Indicating for testing of finished products.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The firm have quaternary gradient HPLC (Shimadzu; Model: LC20AT); with time and date locked but it is not 21CFR Compliant.</td></tr>
<tr><td>31.</td><td>Can you show Audit trail reports?</td><td>Yes, The firm had shown the Audit trail reports.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>Yes, The firm had remaining quantities of stability batches placed in stability chamber for ongoing stability studies. Remaining Quantities as follows:
<table>
<tr><th>Batch #</th><th>Retaining Samples</th><th>For ongoing stability Studies</th></tr>
<tr><td colspan="3">Delanso 30mg Capsules</td></tr>
<tr><td>T-050</td><td>84 Capsules</td><td>133 Capsules</td></tr>
<tr><td>T-051</td><td>70 Capsules</td><td>133 Capsules</td></tr>
<tr><td>T-052</td><td>84 Capsules</td><td>133 Capsules</td></tr>
</table>
<table>
<tr><th>Batch #</th><th>Retaining Samples</th><th>For ongoing stability Studies</th></tr>
<tr><td colspan="3">Delanso 60mg Capsules</td></tr>
<tr><td>T-053</td><td>84 Capsules</td><td>133 Capsules</td></tr>
<tr><td>T-054</td><td>84 Capsules</td><td>133 Capsules</td></tr>
<tr><td>T-055</td><td>70 Capsules</td><td>133 Capsules</td></tr>
</table></td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>Yes, The firm had completed the accelerated stability studies and kept all the three laboratory scale batches of Delanso 30mg and 60mg capsules for long term stability studies.
There were two Stability Chambers with following details:
<u>Stability Chamber No 1 ; for Long Run Studies</u>
Make: Galvano Scientific
Capacity: 400 Liters
Temperature: 30 +- 2C & 65 % RH
<u>Stability Chamber No 2 ; for Accelerated Studies</u>
Make: Dawn Analytical
Capacity: 400 Liters
Temperature: 40 +- 2C & 75 % RH</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipments used in Dexlansoprazole DDR 30mg Capsules production and analysis?</td><td>Yes, The firm had valid calibration status for the equipment used in Delanso 30mg and 60mg Capsules production and analysis.</td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Power backup by UPS & 200kv Generator was available. Digital data logger was not installed for continuous monitoring and control of stability chambers. Storage conditions were being recorded thrice daily manually.</td></tr>
<tr><td>36.</td><td>Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>Yes, The related manufacturing area, equipment, personnel and utilities are GMP compliant (GMP Certificate No.138/2018–DRAP (AD-709919-530) Valid till 11-07-2019.</td></tr>
</table>

Conclusion:-

On the basis of risk-bassed approach, the genuiniess/authenticity of stability data submitted for registration of Delanso 30mg capsules (Dexlansoprazole 30mg) and Delanso 60mg capsules (Dexlansoprazole 60mg) is verifiable to satisfactory level and it seems that M/s Titlis Pharma had performed stability studies.

Related manufacturing area, equipment, personnel and utilities are also rated as GMP compliant to satisfactory level.
Decision: Registration Board decided to approve registration of "Delanso 30mg capsules (Dexlansoprazole 30mg) and Delanso 60mg capsules (Dexlansoprazole 60mg)" with Innovator's specifications by M/s Titlis Pharma. 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. EXEMPTION FROM ONSITE VERIFICATION OF STABILITY DATA:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date	Remarks
479.	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi	Apixo Tablets 2.5mg Each film coated tablet contains: Apixaban...2.5mg Direct Factor Xa Inhibitors	Form 5D 30-07-2017 DUPLICATE DOSSIER PKR 50,000/- 30-06-2017 As per SRO (Firm has submitted attested copy of fee chalan from ABL Karachi along with undertaking)	Eliquis Tablets 2.5mg by Bristol-Myers Squibb Pfizer (**USFDA** Approved) Last GMP Inspection dated 17-12-2018 concluding acceptable level of GMP compliance status	

STABILITY STUDY DATA

Drug	Apixo Tablets 2.5mg		
Name of Manufacturer	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China		
API Lot No.	20171127		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated:0,1,3,6 (months) Real Time: 0,3,6 (months)		
Batch No.	429DS02	429DS03	429DS04
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	08-06-2018	08-06-2018	08-06-2018
No. of Batches	03		
Date of Submission	1666 (25-03-2019)		

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.	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China issued by CFDA, China. The certificate is valid till 03-03-2021.
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.	Firm has submitted ADC attested invoice confirming import of 1 Kg Apixaban from M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China dated 28-12-2017 for Batch No. 20171127
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 onsite inspection report of their product for Arcox (Etoricoxib) Tablets 90mg & 120mg on 17th September, 2018 and was presented in 286th meeting of Registration Board held on 14 – 16th November, 2018. Registration approved the case and the inspection report confirmed following points • The HPLC software is 21CFR Compliant as per recordavailable with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for • Stability chamber. Chambers are controlled and monitoredthrough software having alarm system for alerts as well.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted ADC attested invoice confirming import of 1 Kg Apixaban from M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China dated 28-12-2017 for Batch No. 20171127
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted that they have procured reference standards from the API manufacturer in September 2017 through courier. Firm has also submitted copy of invoice. Documents for procurement of impurity standards is not submitted.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China issued by CFDA, China. The certificate is valid till 03-03-2021. The certificate has been verified from SFDA website.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation report of Apixaban.

6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted copy of COA of API and reference standard.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement 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 provided following remaining quantities for each batch: 429DS02 : 540 Tablets 429DS03 : 540 Tablets 429DS04 : 540 Tablets
	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 3 batches of API as per the conditions of Zone IV-A.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	The firm has submitted that they have used same excipients in their formulation as that of reference product except film coating material. Therefore they have not performed drug-excipient compatibility studies.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution study with reference product but only at 6.8pH phosphate buffer with 0.05% SLS while the FDA recommended method is to test the product in three media including pH 1.2, pH 4.5 and pH 6.8 buffers
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcoming	Response by the firm
The firm has performed comparative dissolution study with reference product but only at 6.8pH phosphate buffer with 0.05% SLS while the FDA recommended method is to test the product in three media including pH 1.2, pH 4.5 and pH 6.8 buffers	Firm has responded that as per assessment report of EMA and USFDA, apixaban belongs to BCS class-III with no reported concerns pertaining to solubility, and that its solubility is not affected by changes in pH. The firm has submitted that it is evident that conducting dissolution study in other pH medium would not have yielded useful scientific information on release of apixaban. Hence we have performed dissolution profile study only in QC release medium.

Decision: Registration Board decided to approve registration of "Apixo Tablets 2.5mg (Apixaban 2.5mg)

with Innovator's specifications by M/s Getz Pharma Pvt. Ltd29-30, Sector 27, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches 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 GMP Inspection Report Date	Remarks
480.	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi	Apixo Tablets 5mg Each film coated tablet contains: Apixaban.....5mg Direct Factor Xa Inhibitors	Form 5D 30-07-2017 DUPLICATE DOSSIER PKR 50,000/- 30-06-2017 As per SRO (Firm has submitted attested copy of fee chalan from ABL Karachi along with undertaking)	Eliquis Tablets 5mg by Bristol-Myers Squibb Pfizer (**USFDA** Approved) Last GMP Inspection dated 17-12-2018 concluding acceptable level of GMP compliance status	

STABILITY STUDY DATA

Drug	Apixo Tablets 5mg		
Name of Manufacturer	M/s Getz Pharma Pvt. Ltd 29-30, Sector 27, Korangi Industrial Area, Karachi		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China		
API Lot No.	20171127		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated:0,1,3,6 (months) Real Time: 0,3,6 (months)		
Batch No.	428DS02	428DS03	428DS04
Batch Size	5000 tablets	5000 tablets	2500 tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	08-06-2018	08-06-2018	08-06-2018
No. of Batches	03		
Date of Submission	1667 (25-03-2019)		

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.	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China issued by CFDA, China. The certificate is valid till 03-03-2021.

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.	Firm has submitted ADC attested invoice confirming import of 1 Kg Apixaban from M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China dated 28-12-2017 for Batch No. 20171127
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 onsite inspection report of their product for Arcox (Etoricoxib) Tablets 90mg & 120mg on 17th September, 2018 and was presented in 286th meeting of Registration Board held on 14 – 16th November, 2018. Registration approved the case and the inspection report confirmed following points • The HPLC software is 21CFR Compliant as per recordavailable with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for • Stability chamber. Chambers are controlled and monitoredthrough software having alarm system for alerts as well.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted ADC attested invoice confirming import of 1 Kg Apixaban from M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China dated 28-12-2017 for Batch No. 20171127
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted that they have procured reference standards from the API manufacturer in September 2017 through courier. Firm has also submitted copy of invoice. Documents for procurement of impurity standards is not submitted.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China issued by CFDA, China. The certificate is valid till 03-03-2021. The certificate has been verified from SFDA website.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation report of Apixaban.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted copy of COA of API and reference standard.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement of excipients used in the formulation of applied product.
8.	List of qualified staff involved in	The firm has submitted List of qualified staff involved in R&D

	product development with relevant experience.	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 provided following remaining quantities for each batch: 429DS02 : 460 Tablets 429DS03 : 460 Tablets 429DS04 : 460 Tablets
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 3 batches of API as per the conditions of Zone IV-A.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	The firm has submitted that they have used same excipients in their formulation as that of reference product except film coating material. Therefore they have not performed drug-excipient compatibility studies.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution study with reference product but only at 6.8pH phosphate buffer with 0.05% SLS while the FDA recommended method is to test the product in three media including pH 1.2, pH 4.5 and pH 6.8 buffers
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcoming	Response by the firm
The firm has performed comparative dissolution study with reference product but only at 6.8pH phosphate buffer with 0.05% SLS while the FDA recommended method is to test the product in three media including pH 1.2, pH 4.5 and pH 6.8 buffers	Firm has responded that as per assessment report of EMA and USFDA, apixaban belongs to BCS class-III with no reported concerns pertaining to solubility, and that its solubility is not affected by changes in pH. The firm has submitted that it is evident that conducting dissolution study in other pH medium would not have yielded useful scientific information on release of apixaban. Hence we have performed dissolution profile study only in QC release medium.

Decision: Registration Board decided to approve registration of "Apixo Tablets 5mg (Apixaban5mg) with Innovator's specifications by M/s Getz Pharma Pvt. Ltd29-30, Sector 27, Korangi Industrial Area, Karachi. Manufacturer will place first three production batches 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 GMP Inspection Report Date	Remarks
481.	M/s Crystolite Pharmaceuticals. Plot No. 1&2, Street No. S-2, National Industrial Zone, Rawat, Rawalpindi.	Nutadol 75mg Tablets Each film coated tablet contains: Tapentadol (as hydrochloride) …75mg Analgesic (Other opioids) Manufacturer's Specifications.	Form 5D Dy No. 3692 Date: 16-04-2019 PKR 50,000/- 26-02-2019 10 x 10's: As per SRO	NUCYNTA TABLETS (**USFDA** Approved) GMP Inspection report conducted on 17th October 2017 concluded that firm is operating at good level of GMP.	

STABILITY STUDY DATA

Drug	Nutadol 75mg Tablets		
Name of Manufacturer	M/s Crystolite Pharmaceuticals. Plot No. 1&2, Street No. S-2, National Industrial Zone, Rawat, Rawalpindi.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co. Ltd., China		
API Lot No.	20171127		
Description of Pack (Container closure system)	3 x 10's Alu-Alu Blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (months) Real Time: 6 (months)		
Frequency	Accelerated:0,1,2,3,4,6 (months) Real Time: 0,3,6 (months)		
Batch No.	001T18	002T18	003T18
Batch Size	600 tablets	600 tablets	600 tablets
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	16-01-2018	18-01-2018	20-01-2018
No. of Batches	03		
Date of Submission	2114 (29-03-2019)		

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.	Firm has submitted copy of GMP certificate of M/s Precise Chemipharma Pvt. Ltd, C-384, T.T.C. Industrial Area, MIDC Village, Pawane, Navi, Mumbai, India issued by Food and Drug Administration Mahrashtra state which is valid upto 10-10-2018
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 ADC attested invoice dated 05-06-2017 confirming import of 1.2 kg Tapentadol hydrochloride, Lot No. 6009122016 from M/s Precise Chemipharma Pvt. Ltd, C-384, T.T.C. Industrial Area, MIDC Village, Pawane, Navi, Mumbai, India.
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 onsite inspection report of their product TENFAMIDE Tablets 25mg on 17th July, 2018 and was presented in 284th meeting of Registration Board. Registration approved the case and the inspection report confirmed following points • The HPLC software is 21CFR Compliant as per recordavailable with the firm. • Audit trail on the testing reports is available. • Adequate monitoring and control are available for Stability chamber.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted ADC attested invoice dated 05-06-2017 confirming import of 1.2 kg Tapentadol hydrochloride, Lot No. 6009122016 from M/s Precise Chemipharma Pvt. Ltd, C-384, T.T.C. Industrial Area, MIDC Village, Pawane, Navi, Mumbai, India.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted undertaking letter from precise chemipharma that working standard is along with shipment of sample.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate of M/s Precise Chemipharma Pvt. Ltd, C-384, T.T.C. Industrial Area, MIDC Village, Pawane, Navi, Mumbai, India issued by Food and Drug Administration Mahrashtra state which is valid upto 10-10-2018
5.	Mechanism for Vendor pre-qualification	Firm has submitted vendor evaluation form filled by Precise Chemipharma Pvt. Ltd.
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted copy of COA of API and reference standard.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted documents for procurement 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	The firm has submitted copy of product development

	& stability testing of trial batches.	protocols.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of all the three Batches. The quantity of tablets finally packed are: 001T18: 483 Tablets 002T18: 488 Tablets 003T18: 483 Tablets
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch: 001T18: 213 Tablets 002T18: 178 Tablets 003T18: 213 Tablets
	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 3 batches of API as per the conditions of Zone IV-A.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used in applied product development
17.	Drug-excipients compatibility studies.	
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution study with reference product at 4.5 pH and 6.8pH, further the dissolution test at 10, 20, 30, 45 and 60 min is also performed.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports for the applied product has been submitted by the firm.

Remarks of the evaluator:

Shortcoming	Response by the firm
Justify the dissolution specification of NLT 80% in 60 minutes, since tapentadol is an immediate release dosage form and the FDA biopharmaceutics review of the reference product suggests dissolution specification as NLT 80-85% in 30 minutes.	Firm has replied that the dissolution specification results of their product Nutadol 75mg tablet at 30 minutes complies with FDA limits defined in biopharmaceutics review. The firm has stated that the specification of their commercial product will be NLT 80-85% in 30 minutes.

Decision: Registration Board decided to approve registration of "Nutadol Tablets 75mg (Tapentadol 75mg)" with Innovator's specifications by M/s Crystolite PharmaceuticalsRawalpindi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case No. 01: Registration Applications for Local Manufacturing of (Human) Drugs.

a. New Cases: -

482.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Esitil Tablet 20mg
	Composition	Each film coated tablet contains:- Escitalopram as Oxalate ……..20mg
	Diary No. Date of R& I & fee	Dy. No. 7655: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Antidepressant (SSRI) selective Serotonin-reuptake inhibitors.
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As approved by the Government/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lexapro 20 mg tablets by Forest, Inc Subsidiary of Forest Laboratories, Inc USA, approved by MHRA of UK
	Me-too status	Citanew 20mg Tablet by Hilton Pharma Karachi
	GMP status	Last inspection was conducted on 05&06-10-2017 for the purpose of renewal of DML and for GMP certificate issuance, wherein the GMP certificate was issued.
	Remarks of the Evaluator.	
	Decision: Approved.	
483.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	CO-FLON Capsule 6mg/25mg
	Composition	Each capsule contains: Olanzapine ……..6mg Fluoxetine HCL eq to Fluoxetine……25mg
	Diary No. Date of R& I & fee	Dy. No. 2673: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Antidepressant, Anti-Psychotic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 14's Blister Pack
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX capsule by Eli Lilly and Company. (USFDA Approved)
	Me-too status	Olanzo – F 6/25 Capsule by M/s Regal Pharmaceuticals.
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
484.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	METAVID Tablet 50mg/1000mg Capsule
	Composition	Each Film coated Tablet contains: Vildagliptin……..50mg Metformin HCl……1000mg
	Diary No. Date of R& I & fee	Dy. No. 7662: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Ant diabetic/ Hypoglycemic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 14s,30's.
	Approval status of product in Reference Regulatory Authorities.	Galvumet 50mg/ 1000mg film-coated tablet by M/s Novartis Pharmaceuticals Australia Pty Limited.
	Me-too status	Galvus Met 50/1000mg tablet of M/s Novartis (Reg. # 066107)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	

485.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Cybix Capsule 30mg
	Composition	Each capsule contains: Duloxetine as enteric coated pellets 17.65% equivalent to Duloxetine.....….. 30mg **Source of pellets:** Surge Labs Pvt. Ltd
	Diary No. Date of R& I & fee	Dy. No. 7670: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	SSNRIs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO 30's
	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 30 mg capsule) by M/s Eli Lilly, USFDA
	Me-too status	Dulan (Duloxetine 30 mg capsule) by M/s Hilton Pharma. (Reg#055447)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
486.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Cybix Capsule 20mg
	Composition	Each capsule contains: Duloxetine as enteric coated pellets 17.65% eq. to Duloxetine….. 20mg Source of pellets: Surge Labs Pvt. Ltd
	Diary No. Date of R& I & fee	Dy. No. 7669: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	SSNRIs
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 14's,
	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 20 mg capsule) by M/s Eli Lilly, USFDA.
	Me-too status	Dulan (Duloxetine 20mg capsule) by M/s Hilton Pharma. (Reg#055446)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
487.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	METAVID Tablet 50mg/850mg Capsule
	Composition	Each Film coated Tablet contains: Vildagliptin……..50mg Metformin HCl……850mg
	Diary No. Date of R& I & fee	Dy. No. 7652: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Anti-Diabetic/ Hypoglycemic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 30's, 1x14's
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/850 by Novartis. (TGA Approved)
	Me-too status	Galvus Met 50mg/850mg Tablet of M/s Novartis (Reg.#066106)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

488.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Rexin Tablet 20mg
	Composition	Each Film coated tablet contains: Paroxetine as HCL……20mg
	Diary No. Date of R& I & fee	Dy No. 7679: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	SSRIs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO 30's, 1x7's,10's,30s
	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
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The reference product contains paroxetine as HCL hemihydrate, and firm mentioned, "Paroxetine HCL" accordingly the firm was asked to correct label claim, adjust the API quantity along with the submission of required fees. The firm in response submitted updated form5, revised master formulation along with fee of Rs. 5000/= with deposit slip No. 0760189 dated 12 March 2019.
	Decision: Approved	
489.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Zitpro Tablet 500mg
	Composition	Each film coated tablet contains: Azithromycin as Dihydrate…….500mg
	Diary No. Date of R& I & fee	Dy. No. 7664: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO 1x10's, 1x06's, 1x12's.
	Approval status of product in Reference Regulatory Authorities.	FDA. Zithromax 500mg by M/s Pfizer.
	Me-too status	Azomax 500mg Tablets by M/s Novartis Reg. No. 45415
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm was asked to correct label claim, as tablet is film coating along with submission of required fees. The firm in response submitted revised updated form5, along with submission of fee of Rs. 5000/= with deposit slip no. 0760190 dated 12th March 2019.
	Decision: Approved.	
490.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Tramacet Tablet 37.5mg/325mg
	Composition	Each Film Coated Tablet contains: Tramadol HCL…….37.5mg Paracetamol……..325mg
	Diary No. Date of R& I & fee	Dy No. 7678: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Opioid analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO 1x10's, 2x10's,
	Approval status of product in Reference Regulatory Authorities.	Tramacet 37.5 mg/ 325 mg film-coated tablets of Grunanthal (USFDA)
	Me-too status	Tonoflex Plus 37.5mg/325mg Reg. No 67163.

	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
491.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Celmed Capsule 200 mg
	Composition	Each Capsule contains: Celecoxib ……200mg
	Diary No. Date of R& I & fee	Dy. No. 7677: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 20's,
	Approval status of product in Reference Regulatory Authorities.	CELEBREX capsule by G.D. Searle (**USFDA** Approved).
	Me-too status	Orthocel 200mg Capsule by M/S Lisko Pharmaceuticals, Karachi.
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's Specifications.	
492.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	CO-FLON Capsule 3mg/25mg
	Composition	Each capsule contains: Olanzapine ……3mg Fluoxetine HCL eq. to Fluoxetine……25mg
	Diary No. Date of R& I & fee	Dy. No. 7672: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Atypical Anti-Psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO 14's, 30's
	Approval status of product in Reference Regulatory Authorities.	Symbyax capsule by Eli Lilly (USFDA Approved).
	Me-too status	Co-Depricap capsule by Nabiqasim Reg.No. 76136
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
493.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	CO-FLON Capsule 12mg/25mg
	Composition	Each capsule contains: Olanzapine ……12mg Fluoxetine HCL eq. to Fluoxetine……25mg
	Diary No. Date of R& I & fee	Dy No. 7674: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Atypical Anti-Psychotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO 10's,
	Approval status of product in Reference Regulatory Authorities.	Symbyax capsule by Eli Lilly USFDA Approved.
	Me-too status	Olanco 12 mg/25mg capsules of M/s Genome (Reg. # 064014).
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
494.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.

	Brand Name +Dosage Form + Strength	Thiorel Capsule 4mg
	Composition	Each Capsule contains: Thiocolchicoside…….4mg
	Diary No. Date of R& I & fee	Dy No. 7675: 28.01.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Muscle relaxant
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 2x10's,
	Approval status of product in Reference Regulatory Authorities.	Myoplege 4mg approved by ANSM approved.
	Me-too status	Colril Capsules by Searl Pharma Reg.No. 39261
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
495.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Pregabin 100mg Capsule
	Composition	Each Capsule contains: Pregabalin…….100 mg
	Diary No. Date of R& I & fee	Dy No. 7657: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Anti-Epileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO 2x7's
	Approval status of product in Reference Regulatory Authorities.	Alzain 100 mg Capsules, Hard by Dr. Reddy's Laboratories (UK) Ltd, approved by MHRA of UK.
	Me-too status	Zeegab 100mg by Hilton Pharma, Karachi. Reg. No. 47360
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
496.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Linvox Tablet 600mg
	Composition	Each Film Coated Tablet contains: Linezolid……600 mg
	Diary No. Date of R& I & fee	Dy No. 7681: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Antibiotics, Oxazolidinone
	Type of Form	Form 5
	Finished Product Specification	Firm had claimed manufacturer's specs.
	Pack size & Demanded Price	As per SRO 1x10's, 1x12's, 1x14's
	Approval status of product in Reference Regulatory Authorities.	Zyvox 600mg Tablet of Pharmacia & Upjohn (USFDA approved).
	Me-too status	Linexa Tablet 600mg by M/s. Cirin Pharma (Reg# 073213)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
497.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd. Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Fobix Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Febuxostat …….40mg
	Diary No. Date of R& I & fee	Dy No. 7680: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Antigout Agent
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's spec.

	Pack size & Demanded Price	As per SRO 2x10's.
	Approval status of product in Reference Regulatory Authorities.	Uloric tablets by Takeda (USFDA Approved).
	Me-too status	Zurig 40mg tablet of M/s Getz Pharma (Reg. # 067290).
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision:Approved with innovator's specification.	
498.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	S-MET Tablet 50mg/1000mg
	Composition	Each Film Coated Tablet contains: Sitagliptin as Phosphate… …….50mg Metformin HCL……..1000mg
	Diary No. Date of R& I & fee	Dy No. 7649: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Anti-diabetic/ hypoglycaemic agents.
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's spec.
	Pack size & Demanded Price	As per SRO 1x10's, 14's,
	Approval status of product in Reference Regulatory Authorities.	Janumet Tablets by Merck (TGA approved).
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084650).
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm was asked to correct label claim as firm did not mention as film coated along with the submission of applicable fee. The firm in response submitted revised Form-5 with fee of Rs.5,000/= with deposit slip no. 0760192, dated 12 March 2019.
	Decision:Approved with innovator's specification.	
499.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Contrazole Capsule 200mg
	Composition	Each capsule contains: Fluconazole …….200mg
	Diary No. Date of R& I & fee	Dy. No. 7659: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's spec.
	Pack size & Demanded Price	As per SRO; 1x4's,
	Approval status of product in Reference Regulatory Authorities.	Azocan 200mg Capsules by FDC International Ltd. MHRA approved.
	Me-too status	Fcozole 200mg Capsules by Medicraft Pharmaceuticals (Pvt.) Ltd. Reg. No. 60237
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
500.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	S-MET Tablet 50mg/500mg
	Composition	Each Film Coated Tablet Contains: Sitagliptin as Phosphate ……50mg Metformin HCL…….500mg
	Diary No. Date of R& I & fee	Dy. No. 7650: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Anti-diabetic/ hypoglycemic agents.
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's spec.
	Pack size & Demanded Price	As per SRO 1x10's, 14's,

	Approval status of product in Reference Regulatory Authorities.	Janumet tablets of (TGA approved).
	Me-too status	Tagipmet XR 50/500 Tablet Reg. No. 84649
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm was asked to mention film coated in label claim along with the applicable fee. The firm in response submitted updated form5 with fee of Rs.5000/= with deposit slip no. 0760193 dated 11.03.2019.
	Decision:Approved with innovator's specification.	
501.	Name and address of Manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Araxone Injection 2gm IV
	Composition	Each vial contains: Ceftriaxone sodium powder eq. to Ceftriaxone……..2gm
	Diary No. Date of R& I & fee	Dy. No. 7666: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x 1's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin IV Injection 2gm By M/s Roche Products Limited (MHRA approved)
	Me-too status	Titan 2gm IV Injection by M/S Macter Pharma (Reg.No. 075825)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
502.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	AMSARTAN 5mg/80 mg Tablet
	Composition	Each Film Coated Tablet contains Amlodipine besylate eq. to Amlodipine……5 mg Valsartan……. 80 mg
	Diary No. Date of R& I & fee	Dy. No. 7660: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Calcium channel blocker/Angiotensin receptor Blocker
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's,28's
	Approval status of product in Reference Regulatory Authorities.	Amlodipine / Valsartan 5 mg / 80 mg film-coated tablets by M/s Winthrop Pharmaceuticals UK Limited MHRA Approved.
	Me-too status	Exforge 5/80mg film coated tablets of M/s Novartis (R# 047569).
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
503.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	AMSARTAN 5mg/160mg Tablet
	Composition	Each Film coated Tablet contains: Amlodipine besylate eq. to Amlodipine ……5 mg Valsartan……. …..160 mg
	Diary No. Date of R& I & fee	Dy. No. 7661: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Calcium channel blocker/Angiotensin receptor Blocker
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's,28's
	Approval status of product in Reference Regulatory Authorities.	Exforge Tablet By Novartis USFDA Approved.
	Me-too status	Valam 5/160mg Tablet of CCL Pharma (Reg#050261)

	GMP status See for dedicated section	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
504.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	METAVID 50mg/500mg Tablet
	Composition	Each Film Coated Tablet contains Vildagliptin ……..50 mg Metformin HCl…….500 mg
	Diary No. Date of R& I & fee	Dy No. 7651: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Hypoglycemic agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO, 30's
	Approval status of product in Reference Regulatory Authorities.	GALVUS MET 50mg/500mg tablets. Swiss-Medics approved.
	Me-too status	Galmet 50mg/500mg Table M/s Vision Pharmaceuticals,
	GMP status	As recorded for above application
	Remarks of the Evaluator	The firm was asked to mention film coated in label claim along with the applicable fee. The firm in response submitted updated form5 with fee of Rs.5000/= with deposit slip no. 0760194 dated 11.03.2019.
	Decision:Approved with innovator's specification.	
505.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	RESPOCURE 250mg Dry Suspension
	Composition	Each 5 ml contains Clarithromycin taste masked granules 27.5 % eq. to Clarithromycin……..250mg Source of granules: Surge Labs Pvt. Ltd
	Diary No. Date of R& I & fee	Dy. No. 7658: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 1x 6ml in 90ml Glass Bottle
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Claritek Tablets of M/s Getz Reg. No 61347
	GMP status	As recorded for above application
	Remarks of the Evaluator	The firm applied for Respocure 250/5ml, but mentioned as Respocure 125/5ml dry suspension. The firm was asked to clarify. The firm in response submitted updated form5 with fee of Rs.5000/= with deposit slip no. 0760195 dated 12 March 2019.
	Decision: Approved.	
506.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	AMSARTAN 10mg/160mg Tablet
	Composition	Each Film Coated Tablet contains Amlodipine besylate eq. to Amlodipine…….. 10mg Valsartan……..160 mg
	Diary No. Date of R& I & fee	Dy. No. 7668: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Calcium channel blocker/Angiotensin receptor Blocker
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Exforge Tablet By Novartis USFDA Approved
	Me-too status	Exforge 10/160mg Film Coated Tablets. Reg. No 47571
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
507.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Cybix Capsule 60mg
	Composition	Each Capsule contains Duloxetine Enteric coated pellets 17.65% eq. to Duloxetine……..60 mg Source of pellets: Surge Labs Pvt. Ltd
	Diary No. Date of R& I & fee	Dy. No. 7671: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Selective Serotonin and Norepinephrine reuptake inhibitors SSNRI's
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO, 10's
	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 60 mg capsule) by M/s Eli Lilly, USFDA
	Me-too status	Duprex Capsule 60mg CCL Pharmaceuticals, Reg. No. 54412
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
508.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	LOXEN 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Lornoxicam ……..4 mg
	Diary No. Date of R& I & fee	Dy No. 7665: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Non-steroidal anti-inflammatory drug (NSAID)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO, 10's,20's
	Approval status of product in Reference Regulatory Authorities.	Xefo 4 mg tablet (EMA approved)
	Me-too status	Acabel 4mg Tablet by M/s Continental Pharma (Reg. No:061603)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
509.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	LOXEN 8mg Tablet
	Composition	Each Film Coated Tablet contains: Lornoxicam ……..8 mg
	Diary No. Date of R& I & fee	Dy. No. 7667: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Non-steroidal anti-inflammatory drug (NSAID)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO, 10's,20's
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg tablet (EMA approved).

	Me-too status	LoxiBar 8mg Tablet Of M/S Barret Hodgson Reg. No. 81193.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with manufacturer's specifications.	
510.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	Celmed Capsule 100mg
	Composition	Each Capsule contains Celecoxib…….100 mg
	Diary No. Date of R& I & fee	Dy No. 7676: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO, 20's
	Approval status of product in Reference Regulatory Authorities.	Celebrex 100 mg capsules, hard by Pfizer Limited. MHRA approved
	Me-too status	Bexicox 100 Capsule by Medipak Ltd, Lahore. Reg. No. 23946
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
511.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	LINVOX 400mg Tablet
	Composition	Each Film Coated Tablet contains Linezolid……400 mg
	Diary No. Date of R& I & fee	Dy No. 7647: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	synthetic antibacterial agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO, 1x 10's &1x 12's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Ecasil Tablet of M/s Sami Pharmaceuticals (Reg. # 067162).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
512.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	ISOFLOX 750mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin hemihydrate USP Eq. Levofloxacin…….750mg
	Diary No. Date of R& I & fee	Dy. No. 7656: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Flouroquinolones antibiotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO, 1x 10's
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Oliza 750 Tablets by M/s UniMark Pharma (Reg.#038004)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with manufacturer's specifications.	
513.	Name and address of manufacturer /	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial

	Applicant	Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	FOBIX 80mg Tablet
	Composition	Each Film Coated Tablet contains Febuxostat……80 mg
	Diary No. Date of R& I & fee	Dy. No. 7646: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Antigout Agent
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO, 2x 10's
	Approval status of product in Reference Regulatory Authorities.	Uloric tablets by Takeda (USFDA Approved).
	Me-too status	Zurig 80mg Tablet of M/s Getz Pharma Pvt Ltd.
	GMP status	As recorded for above application
	Remarks of the Evaluator	The firm mentioned Fobix 80mg on deposit slip but mentioned Uricstat 80mg on Form5, Firm was asked to clarify. The firm was also asked to correct label claim, as firm mentioned uncoated in label claim and submitted formulation for film coating. The firm in response submitted updated form5 with fee of Rs.5000/= with deposit slip No. 0760196 dated 12 March 2019. But submitted deposit slip was mistakenly written as Fobix 40mg and febuxostat 40mg, Firm also submitted undertaking for mistake.
	Decision: Approved with innovator's specification.	
514.	Name and address of manufacturer / Applicant	ARP (Pvt) Ltd Plot 12&12A, Street No W-3, National Industrial Zone (RCCI) Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	TORYX 60mg Tablet
	Composition	Each Film Coated Tablet contains Etoricoxib ……60 mg
	Diary No. Date of R& I & fee	Dy No. 7648: 28.02.2018 PKR 20,000/-: 26.02.2018
	Pharmacological Group	Non-steroidal anti-inflammatory drug (NSAID) selective COX-2 inhibitors.
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO, 10's,20's
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA 60mg Film-Coated Tablets (MHRA approved).
	Me-too status	Etoria 60mg table of M/s Hygeia Pharma, Islamabad (Reg#080818)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
515.	Name and address of manufacturer / Applicant	M/s. Axis Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name +Dosage Form + Strength	Nimsulin Tablets
	Composition	Each Film Coated Tablet contains; Nimesulide…….. 100mg
	Diary No. Date of R& I & fee	Dy No. 9981: 16.03.2018 PKR 20,000/-: 09.03.2018
	Pharmacological Group	Non-steroidal anti-inflammatory drug (NSAID) selective COX-2 inhibitors.
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO, 10's
	Approval status of product in Reference Regulatory Authorities.	Approved by EMA.
	Me-too status	Nims Table 100mg by M/S Sami Pharmaceuticals Reg.No. 26657

	GMP status	Last inspection was conducted on 19th Sep & 3rd October 2018 by panel for the purpose of grant of GMP certificate, panel rated the firm operating at fair level of compliance with GMP and recommended for grant of GMP.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation as "film coated tablet" by reference regulatory authorities adopted by Registration Board in its 275th meeting.	
516.	Name and address of manufacturer / Applicant	M/s. Axis Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name +Dosage Form + Strength	Velamet Tablets 50/850 mg
	Composition	Each Film Coated Tablet contains; Vildagliptin……50mg Metformin Hydrochloride ……850mg
	Diary No. Date of R& I & fee	Dy. No. 9985: 16.03.2018 PKR 20,000/-: 09.03.2018
	Pharmacological Group	Hypoglycaemic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Galvumet Tablet Of (TGA Approved).
	Me-too status	Galvusmet 50mg/850mg Tablet of M/s Novartis Pharma Stein AG, Switzerland. (Reg#066106).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with Innovator's specifications with a shelf life of 18 months.	
517.	Name and address of manufacturer / Applicant	M/s. Axis Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name +Dosage Form + Strength	Velamet tablets 50/1000 mg
	Composition	Each Film Coated Tablet contains; Vildagliptin……50mg. Metformin Hydrochloride ……1000mg
	Diary No. Date of R& I & fee	Dy. No. 9982: 16.03.2018 PKR 20,000/-: 09.03.2018
	Pharmacological Group	Hypoglycemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Galvumet Tablet Of (TGA Approved).
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with Innovator's specifications with a shelf life of 18 months.	
518.	Name and address of manufacturer / Applicant	M/s. Axis Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name +Dosage Form + Strength	Stelomin Tablets
	Composition	Each Film Coated Tablet contains; Sitagliptin as Phosphate……50mg Metformin hydrochloride……..500mg
	Diary No. Date of R& I & fee	Dy. No. 9984 Dated: 16-03-18 Rs.20,000/- Dated: 09-03-18
	Pharmacological Group	Hypoglycemic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA

	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084649).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
519.	Name and address of manufacturer / Applicant	M/s. Axis Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name +Dosage Form + Strength	Stelomin Plus Tablets
	Composition	Each Film Coated Tablet contains; Sitagliptin as phosphate……50mg Metformin Hydrochloride (USP)……1000mg
	Diary No. Date of R& I & fee	Dy. No. 9983: 16.03.2018 PKR 20,000/-: 09.03.2018
	Pharmacological Group	Hypoglycaemic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA.
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg. # 084650).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
520.	Name and address of manufacturer / Applicant	SPL Pharmaceuticals, Plot #4, Phase III, Hattar Industrial Estate Hattar-Pakistan.
	Brand Name +Dosage Form + Strength	Owell 40mg Capsule
	Composition	Each Delayed Release Capsule Contains:- Omeprazole as enteric coated pellets 8.5%.....40mg **Source of pellets:** M/s Vision Pharmaceuticals.
	Diary No. Date of R& I & fee	Dy. No. 11354: 28.03.2018 PKR 20,000/:- 27.03.2018
	Pharmacological Group	Proton Pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Losec 40 mg hard gastro-resistant capsules by AstraZeneca UK Ltd. Approved by MHRA.
	Me-too status	Xempra 40mg Capsule by Nimrall Laboratories Reg. No. 60029.
	GMP status	Panel inspection was conducted on 04.01.2018 for the purpose of renewal of DML and panel unanimously recommended the renewal of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
521.	Name and address of manufacturer / Applicant	SPL Pharmaceuticals, Plot #4, Phase III, Hattar Industrial Estate Hattar-Pakistan.
	Brand Name +Dosage Form + Strength	Rocetec injection 500mg
	Composition	Each vial contains:- Ceftriaxone sodium powder eq. to Ceftriaxone…..500mg
	Diary No. Date of R& I & fee	Dy. No. 11351:- 28.03.2018 PKR 20,000/:- (27.03.2018)
	Pharmacological Group	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.	Approved by USFDA
	Me-too status	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg. #031982).
	GMP status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Approved.	
522.	Name and address of manufacturer / Applicant	SPL Pharmaceuticals, Plot #4, Phase III, Hattar Industrial Estate Hattar-Pakistan.
	Brand Name +Dosage Form + Strength	Mepraz 20mg capsule
	Composition	Each Delayed Release Capsule Contains: Esomeprazole (as magnesium Trihydrate) enteric coated pellets ……..…..20mg **Source of pellets:** M/s Vision Pharmaceuticals.
	Diary No. Date of R& I & fee	Dy. No. 11353: 28.03.2018 PKR 20,000/:- 27.03.2018
	Pharmacological Group	Proton Pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 14's
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole magnesium Capsule 20mg of Mylan Pharmaceuticals USFDA.
	Me-too status	Esomax Capsule 20mg of M/s Martin Dow Pharmaceuticals.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
523.	Name and address of manufacturer / Applicant	SPL Pharmaceuticals, Plot #4, Phase III, Hattar Industrial Estate Hattar-Pakistan.
	Brand Name +Dosage Form + Strength	Q-Mox 400mg Tablets
	Composition	Each film coated tablet contains: Moxifloxacin as HCL…….400mg
	Diary No. Date of R& I & fee	Dy. No. 11353: 28.03.2018 PKR 20,000/:- 27.03.2018
	Pharmacological Group	Fluoroquinolones.
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification.
	Pack size & Demanded Price	1 x 5's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX Tablets of USFDA approved.
	Me-too status	Swismox 400mg Tablet of M/s Swiss, Karachi (Reg.#070659)
	GMP status	As recorded for above application
	Remarks of the Evaluator	The firm applied for Qmox 400mg tablet while attached deposit slip is for Qmox capsule. Firm was asked for clarification. The firm in response submitted undertaking that by mistake capsule was written on deposit slip, and requested to consider and present it before Registration Board.
	Decision: Deferred for seeking opinion of Legal Affair Division.	
524.	Name and address of manufacturer / Applicant	Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Dobro 100mgTablets
	Composition	Each Film Coated Tablet contains; Spironolactone…….100mg
	Diary No. Date of R& I & fee	Dy No. 9979: 16.03.2018 PKR 20,000/:- 14.03.2018
	Pharmacological Group	Potassium Spring Diuretic
	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.	Aldactone of (USFDA approved).
	Me-too status	Spirone 100 mg Tablets M/s Caraway Pharmaceuticals.

	GMP status	GMP inspection was conducted on 14.09.2017 &21.09.2017 and concluded as firm found to be operating at very good level of GMP.
	Remarks of the Evaluator	
	Decision: Approved.	
525.	Name and address of manufacturer / Applicant	Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Dobro Plus Tablets
	Composition	Each Film Coated Tablet contains; Spironolactone…….50mg Furosemide……..20mg
	Diary No. Date of R& I & fee	Dy. No. 9980: 16.03.2018 PKR 20,000/:- 14.03.2018
	Pharmacological Group	Potassium Spring Diuretic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	2 x 10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Osyrol Lasix of Sanofi Aventis, GmbH, Germany.
	Me-too status	Spiromide Tab 20mg/50mg of Searle company.
	GMP status	GMP inspection was conducted on 14.19.2017 &21.09.2017 and concluded as firm found to be operating at very good level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
526.	Name and address of manufacturer / Applicant	Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Dobro 25mg Tablets
	Composition	Each Film Coated Tablet contains; Spironolactone……25mg
	Diary No. Date of R& I & fee	Dy. No. 9978: 16.03.2018 PKR 20,000/:- 14.03.2018
	Pharmacological Group	Potassium Spring Diuretic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	100's: As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Aldactone of (USFDA approved)
	Me-too status	Acclazide Tablets 25mg Tablets M/s Consolidated Chemicals Reg. No. 23843
	GMP status	GMP inspection was conducted on 14.19.2017 &21.09.2017 and concluded as firm found to be operating at very good level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with BP Specefications.	
527.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Recowel 50mg/5ml Injection
	Composition	Each Vial Contains: Rocuronium Bromide……50mg
	Diary No. Date of R& I & fee	Dy No. 11707: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Non-depolarizing neuromuscular blocker
	Type of Form	Form5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 12's
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK

	Me-too status	Esmeron Injection 50mg of M/s Organon Pakistan Pvt. (Reg.#021154)
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of vial manufacturing facility.	
528.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Amlodipril 8mg/5mg
	Composition	Each Tablet Contains: Perindopril Erbumine……..8mg Amlodipine Besylate eq. to Amlodipine…….5mg
	Diary No. Date of R& I & fee	Dy No. 11704: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 10's
	Approval status of product in Reference Regulatory Authorities.	Perindopril ter-butylamine/ Amlodipine CF 8/5mg un-coated tablets (Approved in Netherland)
	Me-too status	Coversam 8/5mg tablet of M/s Servier Research & Pharmaceuticals (Reg.# 065961)
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
529.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Orlimark 120mg capsules
	Composition	Each Capsule Contains:- Orlistat……120mg **Source:-** M/s Vision Pharmaceuticals.
	Diary No. Date of R& I & fee	Dy No. 11702: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Anti-Obesity Agents
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Beacita Capsule by Actavis (MHRA Approved)
	Me-too status	Orlifit Capsule by Getz Pharma Reg. No. 42390
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Deferred for further deliberation regarding stability of Orlistat Pellets.	
530.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Amlodipril 4mg/5mg
	Composition	Each Tablet Contains: Perindopril Erbumine……..4mg Amlodipine Besylate eq. to Amlodipine…….5mg
	Diary No. Date of R& I & fee	Dy No. 11703: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 10's

	Approval status of product in Reference Regulatory Authorities.	Perindopril ter-butylamine/ Amlodipine CF 4/5mg un-coated tablets (Approved in Netherland).
	Me-too status	Coversam 4/5mg tablet of M/s Servier Research & Pharmaceuticals, Pakistan (Reg. # 065962).
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
531.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Recowel 100mg/10ml
	Composition	Each Vial Contains:- Rocuronium Bromide……100mg
	Diary No. Date of R& I & fee	Dy. No. 11708: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Non-depolarizing neuromuscular blocker
	Type of Form	Form5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 12's
	Approval status of product in Reference Regulatory Authorities.	Esmeron Injection By M/S NV Organon, Approved by MHRA.
	Me-too status	Esmeron Injection 50mg of M/s Organon Pakistan (Pvt) (Reg.#021155)
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of vial manufacturing facility.	
532.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Welgard 80mg Tablet
	Composition	Each Tablet Contains:- Nadolol ……..80mg
	Diary No. Date of R& I & fee	Dy. No. 11701: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Non-Selective Beta Blocker
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO, 10's
	Approval status of product in Reference Regulatory Authorities.	Corgard 80mg tablet by Sanofi Aventis(MHRA Approved).
	Me-too status	NALID 80mg Tablets By M/S Genome Pharmaceuticals Hattar.
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
533.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Markcon 100mg
	Composition	Each Capsule Contains:- Itraconazole ……100mg
	Diary No. Date of R& I & fee	Dy. No. 11700: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Itraconazole 100 mg capsules, hard by M/s SandozLimited (MHRA Approved).

	Me-too status	Rolac 100mg Capsules of Sami Pharmaceuticals, Reg.No. 24491.
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	The firm was asked to correct label claim as reference product contains Itraconazole 100 mg and mentioned as Itraconazole 10mg on Form-5 along with the submission of applicable fee. The firm in response submitted that it is typing mistake, whereas in rest of pages it is 100mg and submitted the revised form 5 without submitting applicable fee.
	Decision: Deferred for submission of applicable fee.	
534.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Irofer 500mg/10ml
	Composition	Each ampoule of 10ml Contains:- Iron as ferric carboxymaltose …….500mg
	Diary No. Date of R& I & fee	Dy. No. 11699: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	10 ml ampoule,As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ferinject 50mg/ml (ANSM, France)
	Me-too status	Ferinject 50mg/ml of RG Pharma Reg. No 72548
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	The Firm has claimed reference product which contains 500mg and mentioned on deposit slip is 50mg. Accordingly the firm was asked to submit clarification. The firm in response submitted that by human error they mentioned 50mg instead of 50mg/ml in deposit slip without submission of undertaking.
	Decision: Deferred for submission of applicable fee.	
535.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	De-Cholic 500mg Capsule
	Composition	Each Capsule Contains:- Ursodeoxycholic acid……..500mg
	Diary No. Date of R& I & fee	Dy No. 11706: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Bile acid
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ursochol 500 mg capsule, hard By Orifarm Generics A/S (Sweden Approved).
	Me-too status	Rivsa 500mg Capsule by M/S Martin Dow Ltd Reg. No 82264.
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
536.	Name and address of manufacturer / Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	De-Cholic 250mg Capsule
	Composition	Each Capsule Contains:- Ursodeoxycholic acid……250mg
	Diary No. Date of R& I & fee	Dy No. 11705: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Bile acid

	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ursodeoxycholic acid 250mg Hard Capsules by M/s Strides Pharma UK Ltd MHRA approved.
	Me-too status	Rivsa 250mg Capsule by M/S Martin Dow Ltd Reg. No 82265.
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
537.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Aceril 1.25 mg Tablet
	Composition	Each tablet contains: Ramipril ……1.25 mg
	Diary No. Date of R& I & fee	Dy. No. 11889: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	ACE inhibitor
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	14's, 10's, 20's, 28's,30's ,50's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tritace 1.25 mg tablets By Sanofi Aventis Pharma Ltd. UK. (MHRA Approved).
	Me-too status	Ramipace 1.25 mg Tablet by M/S Pharmevo Ltd. Reg. No. 29172
	GMP status	GMP inspection conducted on 9-11-2017 concluded that firm is working at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Approved with BP Specifications.	
538.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Aceril 2.5 mg Tablet
	Composition	Each tablet contains: Ramipril …….2.5 mg
	Diary No. Date of R& I & fee	Dy No. 11890: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	ACE inhibitor
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	14's, 10's, 20's, 28's,30's ,50's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tritace 2.5 mg tablets By Sanofi Aventis Pharma Ltd. UK. (MHRA Approved).
	Me-too status	Ramipace 2.5 mg Tablet by M/S Pharmevo Ltd. Reg. No. 29173.
	GMP status	GMP inspection conducted on 9-11-2017 concluded that firm is working at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Approved with BP Specifications.	
539.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Aceril 5 mg Tablet
	Composition	Each tablet contains: Ramipril …….5 mg

	Diary No. Date of R& I & fee	Dy. No. 11891: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	ACE inhibitor
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	14's, 10's, 20's, 28's,30's ,50's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tritace 5 mg tablets By Sanofi Aventis Pharma Ltd. UK(MHRA Approved).
	Me-too status	Ramipace 5 mg Tablet by M/S Pharmevo Ltd. Reg. No. 29173
	GMP status	GMP inspection conducted on 9-11-2017 concluded that firm is working at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Approved with BP Specifications.	
540.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Aceril 10 mg Tablet
	Composition	Each tablet contains: Ramipril ……..10 mg
	Diary No. Date of R& I & fee	Dy No. 11892: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	ACE inhibitor
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	14's, 10's, 20's, 28's,30's ,50's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tritace 10 mg tablets By Sanofi Aventis Pharma Ltd. UK. (MHRA Approved).
	Me-too status	Ramipace 10 mg Tablet by M/S Pharmevo Ltd. Reg. No. 34428
	GMP status	GMP inspection conducted on 9-11-2017 concluded that firm is working at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Approved with BP Specifications.	
541.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Folex Tablet
	Composition	Each Chewable tablet contains:- Iron III hydroxide Polymaltose complex eq. to elemental iron----------100mg Folic Acid--------- 0.35mg
	Diary No. Date of R& I & fee	Dy. No. 11885: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	10's , 30's
	Approval status of product in Reference Regulatory Authorities.	Ferrum Fol 100mg/ 350mg chewable Tablets, HPRA Ireland Approved.
	Me-too status	Polymalt F Chewable Tablet by High Q Pharmaceuticals Reg. No. 73606
	GMP status	GMP inspection conducted on 9-11-2017 concluded that firm is working at satisfactory level of GMP compliance.

	Remarks of the Evaluator	Firm applied for chewable tablet and submitted formulation for film coating, accordingly firm was asked to submit clarification. Firm in response submitted revised formulation and submitted fee of Rs.5000/= with deposit No. 0814265 dated 14th March 2019. Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
542.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Clotek50 mg Tablet
	Composition	Each Tablet contains: Clomiphene Citrate ……50mg
	Diary No. Date of R& I & fee	Dy No. 11886: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	Selective Estrogen receptor Modulator, Ovulator Stimulant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's , 50's
	Approval status of product in Reference Regulatory Authorities.	Clomid 50 mg Tablet by Aventis Pharma Limited. (MHRA approved).
	Me-too status	Ovafin 50 mg Tablet by M/s OBS (Reg#019173).
	GMP status	GMP inspection conducted on 9-11-2017 concluded that firm is working at satisfactory level of GMP compliance. The panel has inspected the M/s Innvotek Pharmaceuticals as per following mandate: i- Recommendations for grant of Renewal of DML no.000487. ii- Amendment/changes in existing sections: Tablet section Gen (revised) and Capsule Section (revised) inspection and recommendations. Keeping in view of the above facts on record, the panel unanimously recommends the renewal of DML no.000487 by way of formulation and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised) to M/s Invotek Pharma Islamabad**.**
	Remarks of the Evaluator	As the Product contains Clomiphene citrate and firm mentioned "Clomiphene as citrate" Accordingly firm was asked to submit revised form 5 with submission of applicable fee. If any. The firm in response submitted form 5 with correct label claim and deposit slip of Rs.5000/= with deposit No. 0814266 dated 14th March 2019. The Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: 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.	
543.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Candetar 8 mg Tablet
	Composition	Each tablet contains: Candesartan Cilexetil ……8mg
	Diary No. Date of R& I & fee	Dy. No. 11887: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	Angiotensin II Receptor antagonist
	Type of Form	Form 5

	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	7's, 14's, 28's, 30's , 56's ,70's as per SRO
	Approval status of product in Reference Regulatory Authorities.	Amias Tablet 8 mg by M/S Takeda UK Limited **(**MHRA approved).
	Me-too status	Advant 8 mg Tablet by Getz Pharma Pakistan Reg. No 36059
	GMP status	As recorded for above application
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Approved with Innovator's specifications.	
544.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Candetar 16 mg Tablet
	Composition	Each Tablet contains: Candesartan Cilexetil ……16mg
	Diary No. Date of R& I & fee	Dy. No. 11888: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	Angiotensin II Receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	7's, 14's, 28's, 30's , 56's ,70's as per SRO
	Approval status of product in Reference Regulatory Authorities.	Amias Tablet 8 mg by M/S Takeda UK Limited MHRA approved.
	Me-too status	Advant 16 mg Tablet by Getz Pharma Pakistan Reg. No 34070
	GMP status	As recorded for above application
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section.
	Decision: Approved with Innovator's specifications.	
545.	Name and address of manufacturer / Applicant	Innvotek Pharmaceuticals Plot 35 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Candezide 16/12.5 Tablet
	Composition	Each Tablet Contains:- Candesartan Cilexetil……..16mg Hydrochlorothiazide ……12.5 mg
	Diary No. Date of R& I & fee	Dy No. 11884: 30.03.2018 PKR 20,000/:- 28.03.2018
	Pharmacological Group	Angiotensin II Receptor antagonist Thiazide Diuretic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	7's, 14's, 28's, 20's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan and Hydrochlorothiazide 16/12.5 by MYLAN PHARMS INC, US FDA Approved.
	Me-too status	Advantec 16/12.5 Tablet by Getz Pharma Pakistan Reg.No 39428
	GMP status	As recorded for above application
	Remarks of the Evaluator	Firm has submitted the GMP certificate issued to the firm based on inspection conducted on 30.11.2017. The firm has submitted grant of approval sections/amendments Approval decision for Tablet and Capsule section. The firm applied for uncoated tablet while submitted finish product specification for coated tablet, Firm was asked to clarify. The firm in response submitted revised formulation for uncoated tablet without submission of fee.
	Decision: Approved with Innovator's specifications.	

546.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Topiwen 25mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Topiramate…….25mg
	Diary No. Date of R& I & fee	Dy No. 10678: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anti-epileptic
	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.	Topamax 25 mg film-coated tablets by M/s Janssen-Cilag Limited (MHRA Approved).
	Me-too status	Neutop 25mg Tablet by M/s Nabiqasim (Reg#076387)
	GMP status	GMP inspection conducted on 30-09-2018 & 29-10-2018. Firm is compliant to current Good Manufacturing requirements with need of some improvements which have been discussed and agreed with the management; panel unanimously recommends the grant of GMP certificate.
	Remarks of the Evaluator	
	Decision: Approved.	
547.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Topiwen 100mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Topiramate…100mg
	Diary No. Date of R& I & fee	Dy No. 10679: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anti-epileptic
	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.	Topamax (MHRA approved)
	Me-too status	Engrax Tablets 100mg of M/s English Pharmaceuticals Industries. (Reg# 040144).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
548.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Wendine 5 mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Ivabradine as HCl ……..5mg
	Diary No. Date of R& I & fee	Dy. No. 10703: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Antianginal
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specification
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Corlanor 5mg (US FDA approved).
	Me-too status	Sivab Tablet 5 mg of M/s Getz Pharma (Pvt.) Ltd Reg. No. 76442
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
549.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Wendine 7.5 mg Tablet

	Composition	Each Film-Coated Tablet Contains:- Ivabradine as HCl ……..7.5mg
	Diary No. Date of R& I & fee	Dy No. 10704: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Antianginal
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specification
	Pack size & Demanded Price	As per SRO, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Corlanor 7.5mg (US FDA approved)
	Me-too status	Sivab Tablet 7.5 mg of M/s Getz Pharma Reg. No. 076443
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
550.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Rispowen 1 mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Risperidone……..1mg
	Diary No. Date of R& I & fee	Dy. No. 10681: 22-03-2018 PKR. 20,000/-: 21-03-2018
	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.	Approved by MHRA of UK
	Me-too status	Risperin Tablets 2mg of M/S Hansel Pharma (Reg. # 41346).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
551.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Rispowen 2 mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Risperidone…….2mg
	Diary No. Date of R& I & fee	Dy No. 10681: 22-03-2018 PKR. 20,000/-: 21-03-2018
	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.	Approved by MHRA of UK
	Me-too status	Risperin Tablets 2mg of M/S Hansel Pharma (Reg. # 41347).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
552.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Rispowen 3 mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Risperidone ……..3mg
	Diary No. Date of R& I & fee	Dy. No. 10682: 22-03-2018 PKR 20,000/-: 21-03-2018
	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.	Approved by MHRA of UK
	Me-too status	Risperin Tablets 2mg of M/S Hansel Pharma (Reg. # 41347)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
553.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Rispowen 4 mg Tablet
	Composition	Each Film-Coated Tablet Contains:- Risperidone……4mg
	Diary No. Date of R& I & fee	Dy. No. 10683: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anti-Psychotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, As per SOP
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Apprid Tablets 4mg of M/S Usawa Pharmaceuticals, Risalpur (Reg.# 43322)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
554.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Flozapine 3/25 mg capsule
	Composition	Each Capsule contains:- Olanzapine…….....3 mg Fluoxetine as hydrochloride.....25 mg
	Diary No. Date of R& I & fee	Dy No. 10694: 22-03-2018 PKR 20,000/-: 22-03-2018
	Pharmacological Group	SSRI/Thienbenzodiazepine.
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Symbyax 3 mg/25 mg Capsules of Eli Lilly, USA (USFDA).
	Me-too status	Olanco Capsules by Genome Pharma. (Reg. # 079388).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
555.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Wenvax 37.5 mg Tablet
	Composition	Each Tablet Contains:- Venlafaxine Hydrochloride Eq. to Venlafaxine…37.5mg
	Diary No. Date of R& I & fee	Dy. No. 10695: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Selective serotonin and norepinephrine reuptake inhibitor (SNRI)
	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.	Venlafaxine Hydrochloride 37.5mg tablets by M/s Teva Pharmaceuticals USA (USFDA Approved)
	Me-too status	Amfax 37.5mg Tablets by M/s Amson (Reg#029062)
	GMP status	As recorded for above application

	Remarks of the Evaluator	The firm was asked to clarify that they applied for film coated tablet, and submitted formulation as extended release, whereas approved formulation in reference countries is extended release and uncoated. The firm in response submitted the revised formulation for uncoated tablet along with fee of Rs.5000/ with deposit slip no. 1917516 dated 19.03.2019.
	Decision: Approved.	
556.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Wenvax 50 mg Tablet
	Composition	Each Tablet Contains:- Venlafaxine Hydrochloride Eq. to Venlafaxine……..50mg
	Diary No. Date of R& I & fee	Dy. No. 10696: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Selective serotonin and norepinephrine reuptake inhibitor (SNRI)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Venlafaxine Hydrochloride 50mg extended release tablets by M/s OSMOTICA PHARM USA (USFDA Approved).
	Me-too status	Amfax 50mg Tablets by M/s Amson (Reg#029070)
	GMP status	As recorded for above application
	Remarks of the Evaluator	The firm was asked to clarify that they applied for film coated tablet, and submitted formulation as extended release, whereas approved formulation in reference countries is extended release and uncoated. The firm in response submitted the revised formulation for uncoated tablet along with fee of Rs.5000/ with deposit slip no. 1917515 dated 19.03.2019.
	Decision: Approved.	
557.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Valpine 5/80 mg tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besylate ……5mg Valsartan……..80mg
	Diary No. Date of R& I & fee	Dy. No. 10701: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anti-Hypertensive, Calcium Channel Blocker
	Type of Form	Form-5
	Finished Product Specification	USP specification
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Amlodipine Besylate and Valsartan 5/80 mg of Par Pharm (USFDA).
	Me-too status	Avcard 5/80mg Tablets by Hilton Pharma (Reg. No. 55137)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
558.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Valpine 5/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as besylate……5mg Valsartan……...160mg
	Diary No. Date of R& I & fee	Dy. No. 10700: 22-03-2018 PKR 20,000/-: 22-03-2018
	Pharmacological Group	Anti-Hypertensive, Calcium Channel Blocker

	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge 5 mg/160 mg Film-coated tablets by M/S Novartis (EMA Approved).
	Me-too status	Avcard 5/160 mg Tablets by Hilton Pharma (Reg. No. 55138)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
559.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Valpine 10/160mg tablet
	Composition	Each Film Coated Tablet Contains:- Amlodipine Besylate as Amlodipine…10mg Valsartan……160mg
	Diary No. Date of R& I & fee	Dy. No. 10702: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anti-Hypertensive, Calcium Channel Blocker.
	Type of Form	Form-5
	Finished Product Specification	USP specification
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge 10 mg/160 mg film-coated tablets by Novartis (EMA Approved).
	Me-too status	Avcard 10/160 mg Tablets by Hilton Pharma (Reg. No. 55139)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
560.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Vilmet 50/500mg Tablets
	Composition	Each film coated tablet contains: Vildagliptin……50mg Metformin hydrochloride……..500mg
	Diary No. Date of R& I & fee	Dy No. 10698: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Ant diabetic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/500 film coated tablet by NovartisPharmaceuticals (TGA Australia Approved).
	Me-too status	Galmet 50mg/500mg Tablet by M/S Vision (Reg. No.81905)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
561.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	VILMET 50/850mg Tablets
	Composition	Each Film coated tablet contains: Vildagliptin ……...50mg Metformin Hydrochloride…….850mg
	Diary No. Date of R& I & fee	Dy No. 10697: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Ant diabetic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Galvumet Tablet Of (TGA Approved)

	Reference Regulatory Authorities.	
	Me-too status	Galmet 50mg/500mg Tablet by M/S Vision (Reg. No.81906)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
562.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	VILMET 50/1000mg Tablets
	Composition	Each film coated tablet contains: Vildagliptin……50mg Metformin Hydrochloride…1000mg
	Diary No. Date of R& I & fee	Dy No. 10699: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Ant diabetic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/1000 film coated tablet by NovartisPharmaceuticals (TGA Australia Approved).
	Me-too status	Galmet 50mg/500mg Tablet by M/S Vision (Reg. No.81907)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovators specifications.	
563.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	LINZ 400 mg Tablet
	Composition	Each Film Coated Tablet Contains: Linezolid……400mg
	Diary No. Date of R& I & fee	Dy. No. 10689: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Other Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specification
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox 400 mg tablet by M/s Pharmacia and Upjohn Pharma (USFDA).
	Me-too status	Oxalid 400mg Tablets by M/s Aries Pharma (Reg. No. 82580)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name & with Innovators specifications.	
564.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	LINZ 600 mg Tablet
	Composition	Each film coated tablet contains: Linezolid…600mg
	Diary No. Date of R& I & fee	Dy. No. 10690: 22-03-2018 PKR 20,000/: 21-03-2018
	Pharmacological Group	Other Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specification.
	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	Linox 600 mg Tablet by M/S Nabi Qasim (Reg. No. 81180)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name & with Innovators specifications.	

565.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	LINZ 100mg/5ml Oral Suspension
	Composition	Each 5ml of reconstituted suspension contains: Linezolid…100mg
	Diary No. Date of R& I & fee	Dy. No. 10688: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Antibacterial agent of Oxazolidinone class
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox Dry Suspension by Pharmacia (USFDA Approved).
	Me-too status	Nezolid 100mg Suspension by Searle (Reg. No. 050326).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name & with Innovators specifications.	
566.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Linz 2mg/1ml Infusion
	Composition	Each 100ml Vial contains:- Linezolid……200mg
	Diary No. Date of R& I & fee	Dy. No. 25256: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Oxazolidinone
	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	Linzol Infusion 200mg of M/s Regal Pharma, (Reg.#081997)
	GMP status	As recorded for above application
	Remarks of the Evaluator	Registration Board approved the applied formulation with innovator's specifications in the light of decision taken in 271st meeting, stated as under: "In order to ensure, safety, efficacy and quality of Linezolid infusion, Registration Board decided as under; i) All the Manufacturers of Linezolid Infusion shall follow the packaging instructions of the innovator of the product i.e. M/s Pfizer which has clearly mention the storage precautions in its Product Information Leaflet (PIL).
	Decision: Approved with change of brand name & with Innovators specifications. "**In order to ensure, safety, efficacy and quality of Linezolid infusion, Registration Board decided as under;** **i) All the Manufacturers of Linezolid Infusion shall follow the packaging instructions of the innovator of the product i.e M/s Pfizer which has clearly mention the storage precautions in its Product Information Leaflet (PIL). They will also make sure that the solution is kept correctly in its box and foil wrapping in order to protect from light."**	
567.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Lamowen 25 mg Tablet
	Composition	Each Tablet Contains: Lamotrigine……25mg
	Diary No. Date of R& I & fee	Dy No. 10684: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Lamictal 25mg tablet of M/s GSK (Reg. # 014918) (uncoated).
	GMP status	As recorded for above application
	Remarks of the Evaluator	Firm was asked to clarify that the firm applied for film-coated tablet while the applied formulation in approved in reference countries is uncoated. Firm in response submitted revised formulation along with fee of 5000/ with deposit slip No. 1917511 dated 19.03.2019.
	Decision: Approved.	
568.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Lamowen 50 mg Tablet
	Composition	Each Tablet Contains: Lamotrigine……50mg
	Diary No. Date of R& I & fee	Dy. No. 10685: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lamictal 50 mg tablets by M/s The Wellcome FoundationLtd (MHRA Approved).
	Me-too status	Lamotec Tablets 50 mg by M/s Rotex Medica Pakistan (Pvt) Ltd. (Reg#070154)
	GMP status	As recorded for above application
	Remarks of the Evaluator	Firm was asked to clarify that the firm applied for film-coated tablet while the applied formulation in approved in reference countries is uncoated. Firm in response submitted revised formulation along with fee of 5000/ with deposit slip No. 1917512 dated 19.03.2019.
	Decision: Approved.	
569.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	Lamowen 100 mg Tablet
	Composition	Each Tablet Contains: Lamotrigine…100mg
	Diary No. Date of R& I & fee	Dy No. 10686: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamictal 100 mg tablets by M/s The Wellcome FoundationLtd (MHRA Approved).
	Me-too status	Lamotec Tablets 100 mg by M/s Rotex Medica Pakistan (Pvt) Ltd. (Reg#070155).
	GMP status	As recorded for above application
	Remarks of the Evaluator	Firm was asked to clarify that the firm applied for film-coated tablet while the applied formulation in approved in reference countries is uncoated. Firm in response submitted revised formulation along with fee of 5000/ with deposit slip No. 1917513 dated 19.03.2019.
	Decision: Approved.	
570.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	OLAWEN 5 mg Tablet

	Composition	Each Film Coated Tablet Contains: Olanzapine…5mg
	Diary No. Date of R& I & fee	Dy. No. 10691: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Antipsychotic
	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	Olanzyan 5 mg Tablets of M/s Roryan Pharma (Reg.#78590).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
571.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	OLAWEN 10 mg Tablet
	Composition	Each Film Coated Tablet Contains: Olanzapine…10mg
	Diary No. Date of R& I & fee	Dy. No. 10692: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Olanzyan 5 mg Tablets of M/s Roryan Pharma (Reg. No. 78591).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
572.	Name and address of manufacturer / Applicant	Wenovo Pharmaceuticals Plot 31 & 32 Punjab Small Industrial Estate Taxila Rawalpindi.
	Brand Name +Dosage Form + Strength	FLOZAPINE 25/12 mg capsule
	Composition	Each capsule contains: Fluoxetine HCl eq. to Fluxetine……..25mg Olanzapine……12mg
	Diary No. Date of R& I & fee	Dy. No. 10693: 22-03-2018 PKR 20,000/-: 21-03-2018
	Pharmacological Group	Antipsychotic and SSRI
	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.	Symbyax 12mg/25mg capsule by Eli Lilly (USFDAApproved).
	Me-too status	Olanzakson DS Capsule of M/s Akson (Reg. No. 81658)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
573.	Name and address of manufacturer / Applicant	M/s NovaMed Pharmaceuticals (Pvt) Ltd. 28 Km Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	Diapin 100mg SR tablet
	Composition	Each Sustained Release tablet contains: Diclofenac sodium……100 mg
	Diary No. Date of R& I & fee	Dy. No. 11407: 28-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Voltaren-XR, USFDA Approved.
	Me-too status	Rheunil SR 100mg Tablets by M/s Munawar Pharma Reg.No.024585
	GMP status	Panel inspection was conducted on 22.01.2019 by panel, and concluded as under: "Firm Operating at good level of GMP."
	Remarks of the Evaluator	
	Decision: Approved.	
574.	Name and address of manufacturer / Applicant	"M/s Usawa Pharmaceuticals, Plot No. 146, Special Industrial Zone (EPZ) Risalpur, **contract manufacturing** by M/s Bio Lab (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	**UD-3 Injection 5mg/ml**
	Composition	Each ml Injection contains: Cholecalciferol……5mg (200,000IU)
	Diary No. Date of R& I & fee	Dy. No. 11729: 30-03-2018 PKR 50,000/-: 29-03-2018
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, I x5
	Approval status of product in Reference Regulatory Authorities.	VITAMIN D3 GOOD 200,000 IU / 1 ml IM solution for injection ANSM, France approved
	Me-too status	D-Tres 5mg/ml Injection by M/s Sami (Reg. No. 076115)
	GMP status	Panel Inspection of Applicant: M/s Usawa Pharma.14.10.2016. GMP certificate issued. Panel Inspection of Manufacturer: M/s Bio Lab Pharma. 20.11.2017. "The firm operating at fair compliance with GMP as of today."
	Remarks of the Evaluator	The firm has provided list of already approved products registered for contract manufacturing i.e. 8 products and applied products for contract manufacturing are 2. The firm submitted that they have the following approved sections: 1. Tablet (General Antibiotic) 2. Capsule (General Antibiotic) 3. Capsule (cephalosporin) 4. Dry Powder Suspension (cephalosporin).
	Decision: Approved.	
575.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial Triangle, Kahuta Road Islamabad, **contract manufacturing** by M/s Global Pharmaceuticals (Pvt.) ltd. Plot # 204-205, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Visopen IV Injection 500mg
	Composition	Each vial contains: Meropenum…….500mg
	Diary No. Date of R& I & fee	Dy No. 11651: 30-03-2018 PKR 50,000/-: 27-03-2018
	Pharmacological Group	Anti-Bacterial Carbapenum
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO, 1'S
	Approval status of product in Reference Regulatory Authorities.	Merrem By M/s PFIZER (US FDA) approved.
	Me-too status	Mopen 500mg Injection by M/s Hilton Pharma Reg. No. 36429

	GMP status	Panel Inspection of Applicant: M/s Vision Pharma.11.02.2019. GMP certificate issued. Panel Inspection of Manufacturer: M/s Global Pharma. 11.10.2018 & 24.11.2018.GMP certificate issued.
	Remarks of the Evaluator	API also contains sodium carbonate. The firm has provided list of already approved products registered for contract manufacturing i.e. 17 products and applied products for contract manufacturing are 5. The firm submitted that they have 10 approved sections.
	Decision: Approved.	
576.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial Triangle, Kahuta Road Islamabad, **contract manufacturing** by M/s Global Pharmaceuticals (Pvt.) ltd. Plot # 204-205, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Visopen IV Injection 1000mg
	Composition	Each vial contains: Meropenum…….1000mg
	Diary No. Date of R& I & fee	Dy. No. 11650: 30-03-2018 PKR 50,000/-: 27-03-2018
	Pharmacological Group	Anti-Bacterial Carbapenum
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO, 1'S
	Approval status of product in Reference Regulatory Authorities.	Merrem By M/s PFIZER (US FDA) approved.
	Me-too status	Mopen 1000mg Injection by M/s Hilton Pharma Karachi Reg. No. 36427.
	GMP status	As recorded for above application
	Remarks of the Evaluator	API also contains sodium carbonate. The firm has provided list of already approved products registered for contract manufacturing i.e. 17 products and applied products for contract manufacturing are 5. The firm submitted that they have 10 approved sections.
	Decision: Approved.	
577.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial Triangle, Kahuta Road Islamabad, **contract manufacturing** by M/s Global Pharmaceuticals (Pvt.) ltd. Plot # 204-205, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Enem IV Injection
	Composition	Each vial contains: Imipenem Monohydrate eq. to Imipenem……500mg Cilastin Sodium eq. to Cilastin…….50mg
	Diary No. Date of R& I & fee	Dy. No. 11652: 30-03-2018 PKR 50,000/-: 27-03-2018
	Pharmacological Group	Carbapenem
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO, 1's vial
	Approval status of product in Reference Regulatory Authorities.	Imipenem/Cilastatin 500mg/500mg Powder for Solution for Infusion by M/s STRAVENCON Ltd. (PL-39655/0018). MHRA Approved.
	Me-too status	Cilapen IV Injection by M/s Bosch Pharma. (Reg#048491)
	GMP status	As recorded for above application
	Remarks of the Evaluator	API also contains sodium carbonate. The firm has provided list of already approved products registered for contract manufacturing i.e. 17 products and applied products for contract manufacturing are 5.

		The firm submitted that they have 10 approved sections.
	Decision: Approved.	
578.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial Triangle, Kahuta Road Islamabad, **contract manufacturing** by M/s Global Pharmaceuticals (Pvt.) ltd. Plot # 204-205, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Pizo IV Injection 2.25gm
	Composition	Each Vial Contains: Piperacillin (as Piperacillin Sodium)……2gm Tazobactam (as Tazobactam Sodium)…….0.25gm
	Diary No. Date of R& I & fee	Dy No. 11654: 30-03-2018 PKR 50,000/-: 27-03-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO, 1's
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Tanzo Injection 2.5 gm by Bosch Pharma Reg. No. 039593
	GMP status	As recorded for above application
	Remarks of the Evaluator	API also contains sodium carbonate. The firm has provided list of already approved products registered for contract manufacturing i.e. 17 products and applied products for contract manufacturing are 5. The firm submitted that they have 10 approved sections.
	Decision: Approved with change of name.	
579.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals (Pvt.) Ltd. Plot# 22-23, Industrial Triangle, Kahuta Road Islamabad, **contract manufacturing** by M/s Global Pharmaceuticals (Pvt.) ltd. Plot # 204-205, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Pizo IV Injection 4.5gm
	Composition	Each Vial Contains: Piperacillin (as Piperacillin Sodium)……4gm Tazobactam (as Tazobactam Sodium)……..0.50gm
	Diary No. Date of R& I & fee	Dy No. 11653: 30-03-2018 PKR 50,000/-: 27-03-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO, 1's
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Tanzo Injection 4.5gm by Bosch Pharma Reg. No. 039439
	GMP status	As recorded for above application
	Remarks of the Evaluator	API also contains sodium carbonate. The firm has provided list of already approved products registered for contract manufacturing i.e. 17 products and applied products for contract manufacturing are 5. The firm submitted that they have 10 approved sections.
	Decision: Approved with change of name.	
580.	Name and address of manufacturer / Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Qinreg 200mg Tablet
	Composition	Each tablet contains: Hydroxychloroquine Sulphate……200mg
	Diary No. Date of R& I & fee	Dy. No. 11718: 30-03-2018 PKR 20,000/-: 28-03-2018

	Pharmacological Group	Anti-rheumatic
	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.	Plaquenil 200mg Film coated tablet (MHRA Approved)
	Me-too status	HCQ 200mg tablets of GETZ (Reg. No. 045471).
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated the firm operating at fair level of compliance with GMP as of today.
	Remarks of the Evaluator	The Applied formulation in reference countries agencies is film coated and firm applied for uncoated, however firm submitted formulation for film coated. The firm was asked to correct label claim and submit updated form5. The firm in response submitted same previous form5 for uncoated and did not justify.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
581.	Name and address of manufacturer / Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Lepride 25mg Tablets
	Composition	Each Tablet contains: Levosulpride ……..25mg
	Diary No. Date of R& I & fee	Dy No. 11721: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Antipsychotic
	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.	Levidomed 25mg tablets of M/s Medochemie Ltd. approved by AIFA of Italy.
	Me-too status	Sulvoric 25mg of M/s High-Q, Karachi (Reg. No. 070484).
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated the firm operating at fair level of compliance with GMP as of today.
	Remarks of the Evaluator	Applied formulation in reference countries agencies is film coated and firm applied for uncoated. The firm was asked to clarify. Firm in response submitted same form5, formulation for uncoated tablets.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
582.	Name and address of manufacturer / Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Lepride 50 mg Tablets
	Composition	Each Tablet contains: Levosulpride ……50mg
	Diary No. Date of R& I & fee	Dy No. 11719: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Antipsycotic
	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.	Levidomed 50mg tablets of M/s Medochemie Ltd. approved by AIFA of Italy.
	Me-too status	Sulvoric 50mg of M/s High-Q, Karachi (Reg.#070485)
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated as "The firm operating at fair level of compliance with GMP as of today."
	Remarks of the Evaluator	Applied formulation in reference agencies is film coated and firm applied for uncoated. The firm was asked to clarify. Firm in response submitted same form5, formulation for uncoated tablets.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
583.	Name and address of manufacturer / Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Cine 1mg Tablet
	Composition	Each tablet contains: Cinitapride hydrogen tartrate eq. to cinitapride…1mg
	Diary No. Date of R& I & fee	Dy No. 11720: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Propulsives Antidopaminergic prokinetic
	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.	Cidine 1 mg uncoated tablet by ALMIRALL, SA (Spain Approved)
	Me-too status	Cidine Tablets by Highnoon Lab (Reg#052940).
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated as "The firm operating at fair level of compliance with GMP as of today."
	Remarks of the Evaluator	Applied formulation in reference agencies is film coated and firm applied for uncoated. The firm was asked to clarify. Firm in response submitted same form5, formulation for uncoated tablets.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
584.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Orfit 120mg Capsule
	Composition	"Each Capsule Contains: Orlistat……120mg"
	Diary No. Date of R& I & fee	Dy. No 14095 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Lipase inhibitor
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	3 x10, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Beacita Capsule by Actavis (MHRA Approved).
	Me-too status	Orlifit Capsule by Getz Pharma Reg. No. 42390

	GMP status	Panel inspection was conducted on 20.09.2017 for the purpose of renewal of DML, and concluded as under:- "After thorough evaluation of documents and inspection of the unit, panel decided to recommend the renewal of DML.
	Remarks of the Evaluator	• Submit source of Pellets. • Submit Stability studies, Master formula & GMP of source. • Firm did not reply yet.
	Decision: Deferred for following: • **Submit source of Pellets.** • **Submit Stability studies, Master formula & GMP of source.**	
585.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Linzold 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…….400mg"
	Diary No. Date of R& I & fee	Dy.No 14099 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Antibacterial, Oxazolidinone
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	1 x10, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Ecasil Tablet of M/s Sami Pharmaceuticals (Reg. # 067162)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
586.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore."
	Brand Name +Dosage Form + Strength	Linzold 600mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…600mg"
	Diary No. Date of R& I & fee	Dy.No 14100 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Antibacterial, Oxazolidinone
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	1 x10, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox 600mg Tablet of Pharmacia & Upjohn (USFDA approved)
	Me-too status	Linexa Tablet 600mg by M/s. Cirin Pharma (Reg. # 073213)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
587.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore."
	Brand Name +Dosage Form + Strength	Linzold 100mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Linezolid…100mg"
	Diary No. Date of R& I & fee	Dy.No 14098 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Antibacterial, Oxazolidinone
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	60ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox Dry Suspension by Pharmacia (USFDA Approved)
	Me-too status	Nezolid 100mg Suspension by Searle (Reg. No. 050326)

	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
588.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore."
	Brand Name +Dosage Form + Strength	3D Syrup
	Composition	"Each 10ml Contains: Vitamin D3……..1000 IU"
	Diary No. Date of R& I & fee	Dy.No 14094 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Multivitamin
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	120ml
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Me-too could not be verified.
	GMP status	As recorded for above application
	Remarks of the Evaluator	Submit Me-too status with documentary evidence. Submit International availability from reference countries agencies.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
589.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore."
	Brand Name +Dosage Form + Strength	Kuin-Kid 125mg Dry Powder Suspension
	Composition	"Each 5ml Contains: Ciprofloxacin HCL Eq. to Ciprofloxacin…….125mg"
	Diary No. Date of R& I & fee	Dy.No 14096 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Antibacterial, Quinolones
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	60ml
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Hiflox Dry suspension of M/s Hilton Pharma (Reg. # 067498).
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
590.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore."
	Brand Name +Dosage Form + Strength	Kuin-Kid 250mg Dry Powder Suspension
	Composition	"Each 5ml Contains: Ciprofloxacin HCL Eq. to Ciprofloxacin……..250mg"
	Diary No. Date of R& I & fee	Dy.No 14097 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Antibacterial, Quinolones
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	60ml
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Hiflox Dry suspension of M/s Hilton Pharma (Reg. # 067499).
	GMP status	As recorded for above application
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications. Diluent shall be provided as per innovator's product.	
591.	Name and address of manufacturer / Applicant	"M/s P.D.H Pharmaceuticals Pvt Ltd. 19 km, Ferozepur Road, Lahore."
	Brand Name +Dosage Form + Strength	Eazyflow 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rivaroxaban……10mg"
	Diary No. Date of R& I & fee	Dy. No 14093 dated 16-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Anti-Thrombic agent
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	1 x10, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 10 mg film-coated tablets by Milpharm Limited. MHRA approved.
	Me-too status	Xaroban 10mg Tablet by M/s The Searle Company Ltd Kar. Reg. No. 76284.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name and with innovator's specifications	
592.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Windom 10mg Tablet
	Composition	"Each Film CoatedTablet Contains: Domperidone……..10mg"
	Diary No. Date of R& I & fee	Dy. No 14486 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Antiemetic
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Epodom 10mg Tablets of M/s Atlantic Pharmaceutical (Pvt.) Ltd, (Reg. 062326).
	Me-too status	Approved by TGA of Australia.
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
593.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Winralex 10mg Tablet
	Composition	"Each Film coated Tablet Contains: Escitalopram as Escitalopram Oxalate…….10mg"
	Diary No. Date of R& I & fee	Dy. No 14483 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	CIPRALEX 10 mg film-coated tablets, by H. Lundbeck A/S. approved by MHRA.
	Me-too status	Zavesca 10mg Tablets by Getz Pharma, Reg. No. 45279
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	

	Decision: Approved.	
594.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Zolowin 20mg Capusle
	Composition	"Each Capsule Contains: Omperazole…….20mg Sodium Bicarbonate……1100mg"
	Diary No. Date of R& I & fee	Dy. No 14484 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Proton Pump Inhibitors/Antacid
	Type of Form	Form5
	Finished Product Specification	Manufacturer's spec.
	Pack size & Demanded Price	5's, 10's, 14's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Encid 20mg by M/s Wilson Pharma Reg. No. 70224
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
595.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Zolowin 40mg Capusle
	Composition	"Each Capsule Contains: Omperazole……..40mg Sodium Bicarbonate……1100mg"
	Diary No. Date of R& I & fee	Dy. No 14485 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Proton Pump Inhibitors/Antacid
	Type of Form	Form5
	Finished Product Specification	Manufacturer's spec.
	Pack size & Demanded Price	5's, 10's, 14's, 20's, 30's. As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Encid 40mg by M/s Wilson Pharma Reg. No. 70225
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
596.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Tifany 1mg Tablet
	Composition	"Each Tablet Contains: Ketotifen as Hydrogen Fumarate…….1mg"
	Diary No. Date of R& I & fee	Dy. No 14482 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Other Antihistamines
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's spec.
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZADITEN Tablets 1mg by Alfasigma S.P.A. MHRA approved.
	Me-too status	Aria Tablet by m/s Highnoon laboratories Reg. No. 14742
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	

	Decision: Approved with innovator's specifications.	
597.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Rifaxiwin 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rifaximin…….200mg"
	Diary No. Date of R& I & fee	Dy. No 14261 dated 17-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	Xifaxan film coated tablet USFDA Approved.
	Me-too status	Nimixa 200mg By Getz Pharma.(Reg.#070734)
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
598.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Rifaxiwin 550mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rifaximin……..550mg"
	Diary No. Date of R& I & fee	Dy. No 14262 dated 17-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	Xifaxan film coated tablet USFDA Approved.
	Me-too status	Nimixa 550mg By Getz Pharma. (Reg. No. 070733).
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
599.	Name and address of manufacturer / Applicant	"M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Wincer Capsule 50MG
	Composition	"Each Capsule Contains: Diacerein…….50mg"
	Diary No. Date of R& I & fee	Dy. No 14260 dated 17-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Anti- Inflammatory Agent
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	5's, 10's, 20's, 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 Lab (R#071639)
	GMP status	GMP inspection was conducted on 14.09.17 and GMP compliance rated as good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
600.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Sem 1mg Tablet

	Composition	"Each Film Coated Tablet Contains: Eszopiclone……..1mg"
	Diary No. Date of R& I & fee	Dy. No 13991 dated 13-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Benzodiazepine related drugs
	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.	Lunesta Tablet by Sunovion Pharms (USFDA Approved)
	Me-too status	Clonexa 1mg Tablet by M/s Atco Laboratories Ltd R.No. 58428.
	GMP status	The firm was inspected on 19.09.2017 & 21.09.2017 & concluded as: - "The firm operating at very good level of GMP."
	Remarks of the Evaluator	
	Decision: Approved.	
601.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Sem 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Eszopiclone……..2mg"
	Diary No. Date of R& I & fee	Dy. No 13992 dated 13-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Benzodiazepine related drugs
	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.	Lunesta Tablet by Sunovion Pharms (USFDA Approved).
	Me-too status	Clonexa 1mg Tablet by M/s Atco Laboratories Ltd R.No. 58429.
	GMP status	The firm was inspected on 19.09.2017 & 21.09.2017 & concluded as: - "The firm operating at very good level of GMP."
	Remarks of the Evaluator	
	Decision: Approved.	
602.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Sem 3mg Tablet
	Composition	"Each Film Coated Tablet Contains: Eszopiclone……..3mg"
	Diary No. Date of R& I & fee	Dy. No 13993 dated 13-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Benzodiazepine related drugs
	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.	Lunesta Tablet by Sunovion Pharms, (USFDA Approved).
	Me-too status	Clonexa 1mg Tablet by M/s Atco Laboratories Ltd R.No. 58430
	GMP status	The firm was inspected on 19.09.2017 & 21.09.2017 & concluded as: - "The firm operating at very good level of GMP."
	Remarks of the Evaluator	
	Decision: Approved.	
603.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Grip 20mg/ml Oral Drops
	Composition	"Each ml Contains: - Escitalopram as (Escitalopram Oxalate)……20mg"
	Diary No. Date of R& I & fee	Dy. No 13990 dated 13-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	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.	Anisdis 20 mg/ml oral drops by Pharmacare, (MHRA Approved).
	Me-too status	Cipralex 20g/ml Drops by M/s Lundbeck Pakistan 9pvt) Ltd. Reg. No. 066177
	GMP status	The firm was inspected on 19.09.2017 & 21.09.2017 & concluded as: - "The firm operating at very good level of GMP."
	Remarks of the Evaluator	Me-too could not be verified from available database. Firm was asked to submit me-too evidence. Firm in reply submitted the evidence, which was verified from available me-too data base.
	Decision: Approved	
604.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Grip 10mg/ml Oral Drops
	Composition	"Each ml Contains: - Escitalopram as (Escitalopram Oxalate)……..10mg"
	Diary No. Date of R& I & fee	Dy. No 13989 dated 13-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	15ml, 30ml, 60ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	International availability could not be verified.
	Me-too status	Citanew Oral Drops by M/s Hilton Pharma Reg. No. 47485
	GMP status	The firm was inspected on 19.09.2017 & 21.09.2017 & concluded as: - "The firm operating at very good level of 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.	
605.	Name and address of manufacturer / Applicant	"M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Incosta 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Domperidone Maleate Eq. to Domperidone…10mg"
	Diary No. Date of R& I & fee	Dy. No 14494 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Dopamine antagonist
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	5×10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TGA Australia Approved.
	Me-too status	Epodom 10mg Tablets of M/s Atlantic Pharmaceutical (Pvt.) Ltd, (Reg.# 062326).
	GMP status	13.07.17 & 16.07.17. Panel concluded as: Firm was considered to be operating at an acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name and innovator's specifications.	
606.	Name and address of manufacturer / Applicant	"M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Sukoon Tablet 300mg
	Composition	"Each Enteric Coated Tablet Contains: Acetyl Salicyclic Acid (Aspirin)……300mg"
	Diary No. Date of R& I & fee	Dy. No 14506 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018

	Pharmacological Group	NSAIDs
	Type of Form	Form5
	Finished Product Specification	BP
	Pack size & Demanded Price	3×10's, As per approved.
	Approval status of product in Reference Regulatory Authorities.	Aspirin 300mg tablet By M/s Alliance Pharmaceuticals (MHRA Approved)
	Me-too status	Me-Too status could not be verified from available data base.
	GMP status	13.07.17 & 16.07.17. Panel concluded as: Firm was considered to be operating at an acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	Firm was asked to provide Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. Firm in reply submitted only Me-too without providing international availability evidence, however given me-too is also uncoated and firm applied for enteric coated.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
607.	Name and address of manufacturer / Applicant	"M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Pass 3.35g/5ml Syrup
	Composition	"Each 5ml Contains: Lactulose…….3.35g"
	Diary No. Date of R& I & fee	Dy. No 14496 dated 18-04-2018 Rs.100,000/- Dated 17-04-2018
	Pharmacological Group	Laxative
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	120ml, 240ml. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duphalac syrup (MHRA approved)
	Me-too status	Laxum Syrup of M/s Hisun Pharmaceuticals, Swabi R.No. 64054.
	GMP status	13.07.17 & 16.07.17. Panel concluded as: Firm was considered to be operating at an acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	Validity of attached supplier's GMP is 12/2015.
	Decision: Deferred for provision of GMP of manufacturer of lactulose.	
608.	Name and address of manufacturer / Applicant	"M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Combact 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Moxifloxacin…400mg"
	Diary No. Date of R& I & fee	Dy. No 14495 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification.
	Pack size & Demanded Price	1×5's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	AVELOX Tablets of USFDA approved
	Me-too status	Swismox 400mg Tablet of M/s Swiss, Karachi (Reg.#070659)
	GMP status	13.07.17 & 16.07.17. Panel concluded as: Firm was considered to be operating at an

		acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name and innovator's specification.	
609.	Name and address of manufacturer / Applicant	"M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	H2Block 150mg Tablet
	Composition	"Each Film coated Tablet Contains: Ranitidine as HCL…….150mg"
	Diary No. Date of R& I & fee	Dy. No 14497 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	H2 receptor antagonist
	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	Ranidol Tablets 150mg of M/s Fedro Pharmaceutical (R#079257)
	GMP status	13.07.17 & 16.07.17. Panel concluded as: Firm was considered to be operating at an acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator	
	Decision: Approved.	
610.	Name and address of manufacturer / Applicant	"M/s Ray Pharma Pvt. Ltd. S-58, S.I.T.E Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Lotemax-T Eye Drops
	Composition	"Each ml Contains: Loteprednol Etabonate……5mg Tobramycin…….3mg"
	Diary No. Date of R& I & fee	Dy. No 14487 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	Antibiotic & Corticosteroids.
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	1×5ml,
	Approval status of product in Reference Regulatory Authorities.	Zylet of (USFDA approved).
	Me-too status	Lotepred-T Ophthalmic Suspension by M/s Elko Pharma Pakistan.70515
	GMP status	14.03.2018, The firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator	The firm was asked to Submit documentary evidence for separate dispensing hood for ophthalmic steroidal products.
	Decision: Deferred for following: • **Submit documentary evidence for separate dispensing hood for ophthalmic steroidal products.**	
611.	Name and address of manufacturer / Applicant	"M/s Ray Pharma Pvt. Ltd. S-58, S.I.T.E Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Eitane Oral Drops
	Composition	"Each ml Contains: Polyethylene glycol……4mg Propylene Glycol……3mg"
	Diary No. Date of R& I & fee	Dy. No 14488 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	Lubricant
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	15ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Systane of Alcon, UK, OTC product (Daily Med)
	Me-too status	Corniwet Eye Solution of M/s Medicaids. # 076375

	GMP status	14.03.2018, The firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
612.	Name and address of manufacturer / Applicant	"M/s Ray Pharma Pvt. Ltd. S-58, S.I.T.E Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Inflanec Eye Drops
	Composition	"Each ml Contains: Nepafenac……..1mg"
	Diary No. Date of R& I & fee	Dy. No 14489 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	5ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVANEP sterile ophthalmic suspension of ALCON Labs , USA
	Me-too status	NEPATEK 0.1% Sterile Ophthalmic suspension.
	GMP status	14.03.2018, The firm is operating at Good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
613.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Aczol 100mg Capsule
	Composition	"Each Capsule Contains: Itraconazole……100mg"
	Diary No. Date of R& I & fee	Dy. No 14269 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Antifungal
	Type of Form	Form5
	Finished Product Specification	The Firm has claimed manufacturer's spec.
	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	Rolac 100mg Capsules of Sami Pharmaceuticals, Reg. No. 24491
	GMP status	03.08.2017, The firm is operating at an acceptable level of compliance of GMP requirements at the time of inspection.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
614.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Glytec-M XR 50/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as Phosphate……..…50mg Metformin HCL……..500mg"
	Diary No. Date of R& I & fee	Dy. No 14273 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form5
	Finished Product Specification	The Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Janumet Tablets by Merck (TGA approved).
	Me-too status	Tagipmet XR 50/500 Table M/s Highnoon Labs Reg. No. 84649.
	GMP status	03.08.2017, The firm is operating at an acceptable level of compliance of GMP requirements at the time of inspection.

	Remarks of the Evaluator	Firm was asked to correct label claim. The firm has applied for sustained release and also submitted formulation for sustained released. Accordingly firm was asked to submit COA, stability study data of three batches conducted in Zone IV-A.
	Decision: Deferred for following: • **Revision of label claim as per the reference product along with the submission of requisite fee.** • **Correct pharmacological group.** • **Submission of stability studies data of three batches as per Registration Board guidelines approved in 278th meeting.**	
615.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Glytec-M XR 50/1000 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate……..50mg Metformin HCL……1000mg"
	Diary No. Date of R& I & fee	Dy. No 14274 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form5
	Finished Product Specification	The Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Janumet Tablets by Merck (TGA approved).
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084650)
	GMP status	03.08.2017, The firm is operating at an acceptable level of compliance of GMP requirements at the time of inspection.
	Remarks of the Evaluator	Firm was asked to correct label claim. The firm has applied for sustained release and also submitted formulation for sustained released. Accordingly firm was asked to submit COA, stability study data of three batches conducted in Zone IV-A.
	Decision: Deferred for following: • **Revision of label claim as per the reference product along with the submission of requisite fee.** • **Correct pharmacological group.** • **Submission of stability studies data of three batches as per Registration Board guidelines approved in 278th meeting.**	
616.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Glytec-M XR 100/1000 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin Phosphate Monohydrate……100mg Metformin HCL……1000mg"
	Diary No. Date of R& I & fee	Dy. No 14275 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form5
	Finished Product Specification	The Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	14's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Janumet Tablets by Merck (TGA approved)
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084651)
	GMP status	03.08.2017, The firm is operating at an acceptable level of compliance of GMP requirements at the time of inspection.
	Remarks of the Evaluator	Firm was asked to correct label claim. The firm has applied for sustained release and also submitted formulation for sustained released. Accordingly firm was asked to submit COA, stability study data of three batches conducted in

		Zone IV-A.
	• **Decision: Deferred for following:** • **Revision of label claim as per the reference product along with the submission of requisite fee.** • **Correct pharmacological group.** • **Submission of stability studies data of three batches as per Registration Board guidelines approved in 278th meeting.**	
617.	Name and address of manufacturer / Applicant	"M/s Rasco Pharma. 5.5 Km, Raiwind Road, Lahore."
	Brand Name +Dosage Form + Strength	Topzol 20mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Pantoprazole Sodium Sesquihydrate Eq. to Pantoprazole……20mg"
	Diary No. Date of R& I & fee	Dy. No 14079 dated 16-04-2018 Rs.20,000/- Dated 16-04-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form5
	Finished Product Specification	The Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO. 14's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved present as Protinix Delayed release tablet
	Me-too status	Panzet 20mg gastro resistant (Enteric coated) Tablet Reg # 081050
	GMP status	GMP certificate issued on the basis of inspection dated 22.02.2018.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
618.	Name and address of manufacturer / Applicant	"M/s Rasco Pharma. 5.5 Km, Raiwind Road, Lahore."
	Brand Name +Dosage Form + Strength	Topzol 40mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Pantoprazole Sodium Sesquihydrate Eq. to Pantoprazole……40mg"
	Diary No. Date of R& I & fee	Dy. No 14080 dated 16-04-2018 Rs.20,000/- Dated 16-04-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form5
	Finished Product Specification	The Firm has claimed manufacturer's spec.
	Pack size & Demanded Price	As per SRO. 14's.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved present as Protinix Delayed release tablet.
	Me-too status	Pantberg 40mg enteric coated Tablet Reg # 079782
	GMP status	GMP certificate issued on the basis of inspection dated 22.02.2018.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications and change of brand name.	
619.	Name and address of manufacturer / Applicant	"M/s Rasco Pharma. 5.5 Km, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Le-Tact 500mg/5ml Injection
	Composition	"Each Ampoule Contains: Levetiracetam…….500mg"
	Diary No. Date of R& I & fee	Dy. No 14075 dated 16-04-2018 Rs.20,000/- Dated 16-04-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×5ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	KEPPRA 500mg/5ml Injection of USFDA approved
	Me-too status	Lumark Injection M/s Searle Pak Reg. No.75873

	GMP status	GMP certificate issued on the basis of inspection dated 22.02.2018.
	Remarks of the Evaluator	
	Decision: Approved.	
620.	Name and address of manufacturer / Applicant	"M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad."
	Brand Name +Dosage Form + Strength	Piroxiwin 20mg Dispersible Tablet
	Composition	"Each Tablet Contains: Piroxicam Beta Cyclodextrin Eq. to Piroxicam……20mg"
	Diary No. Date of R& I & fee	Dy. No 14286 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-inflammatory and ant rheumatic products, non-steroids (oxicams)
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	2×10. As per SRO
	Approval status of product in Reference Regulatory Authorities.	CYCLADOL 20 mg scored tablet. ANSM approved.
	Me-too status	Utrahit-beta Tablet. Reg. No. 81355
	GMP status	14.07.2017. Panel Inspection report. The firm is operating at Fair level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications.	
621.	Name and address of manufacturer / Applicant	"M/s Winilton Pharmaceuticals Pvt Ltd. Plot No.45, Street No. S-5, National Industrial Zone, Rawat, Islamabad."
	Brand Name +Dosage Form + Strength	Lorex 8mg Tablets
	Composition	"Each Film Coated Tablet Contains: Lornoxicam……8mg"
	Diary No. Date of R& I & fee	Dy. No 14284 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	10's Tablets. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Approved by EMA
	Me-too status	RecamTablet 8 mg by M/s Regal Pharmaceuticals (Reg.#081952)
	GMP status	14.07.2017. Panel Inspection report. The firm is operating at Fair level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications.	
622.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar."
	Brand Name +Dosage Form + Strength	Sayfon 40/0.04 mg Injection
	Composition	"Each 4ml Ampoule Contains: Phloroglucinol Hydrate……40mg Trimethyl phloroglucinol…….0.04mg"
	Diary No. Date of R& I & fee	Dy. No 14476 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	Gastrointestinal Anticholinergic
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SPASFON, solution for injection in ampoule by M/s TEVA HEALTH, (ANSM Approved)
	Me-too status	Spasfon Injection 4ml by M/s Himont (Reg. # 018530).
	GMP status	13th Feb 2018. The firm is considered to be operated at acceptable level of compliance with GMP guidelines as per

		Drugs Act 1976.
	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.	
623.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar."
	Brand Name +Dosage Form + Strength	Sayfon 80/80 mg Tablet
	Composition	"Each Sugar Coated Tablet Contains: Phloroglucinol DiHydrate ……..80mg Trimethyl phloroglucinol……80mg"
	Diary No. Date of R& I & fee	Dy. No 14477 dated 18-04-2018 Rs.20,000/- Dated 18-04-2018
	Pharmacological Group	Gastrointestinal Anticholinergic
	Type of Form	Form5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Anafortan plus tablet of M/s AGP Ltd. Karachi. Reg. No. 24504
	GMP status	As recorded for above application
	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.	
624.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar."
	Brand Name +Dosage Form + Strength	B-Carb 5% 1ml Injection
	Composition	"Each ampoule of 1ml Contains: Sodium Bicarbonate…….50mg"
	Diary No. Date of R& I & fee	Dy. No 14088 dated 16-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Irrigating solution.
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	1ml×10 ampoule. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	WHO recommended diluent for Artesunate Injection.
	Me-too status	Dasura 50mg/ml Injection by M/s Mediate Pharmaceutical (Pvt.) Ltd (Reg#061962)
	GMP status	04-09-2018 & 26-09-2018. The panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator	
	Decision: Approved with BP specifications.	
625.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar."
	Brand Name +Dosage Form + Strength	B-Carb 5% 100mg/2ml Injection
	Composition	"Each ampoule of 2ml Contains: Sodium Bicarbonate…….100mg"
	Diary No. Date of R& I & fee	Dy. No 14088 dated 16-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Irrigating solution.
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	2ml×10 ampoule. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Recommended in WHO list, as separate ampoule of 5% sodium bicarbonate solution diluent for Artesun 120 mg injection.
	Me-too status	Sodium bicarbonate injection of M/s Genix Pharma (Reg#061962)
	GMP status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Approved with BP Specifications.	
626.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Xynosine-F Nasal Spray
	Composition	"Each ml Contains: Fluticasone Propionate……50mcg"
	Diary No. Date of R& I &fee	Dy. No 14265 dated 17-04-2018 Rs.20,000/- Dated 16-04-2018
	Pharmacological Group	Decongestants (Corticosteroid)
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	15ml. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Flixonase Aqueous Nasal Spray by M/s GlaxoSmithKline UK (MHRA Approved).
	Me-too status	Flexosone Nasal Spray by "Schazoo Laboratories, R.No 40863.
	GMP status	GMP certificate issued on 23-05-2018.
	Remarks of the Evaluator	
	Decision: Approved with BP specifications.	
627.	Name and address of manufacturer / Applicant	"M/s Werrick Pharmaceuticals. 216-217, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Gluset Plus 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate……..50mg Metformin HCL…….500mg"
	Diary No. Date of R& I & fee	Dy. No 13710 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Anti-diabetic/ hypoglycemic agents.
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	10's, 20's, 60's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Janumet Tablets by Merck (TGA approved).
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084649)
	GMP status	07.12.2017 Very good level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's Specifications.	
628.	Name and address of manufacturer / Applicant	"M/s Werrick Pharmaceuticals. 216-217, I-10/3, Industrial Area, Islamabad."
	Brand Name +Dosage Form + Strength	Gluset Plus 1000mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as Phosphate Monohydrate……50mg Metformin HCL…….1000mg"
	Diary No. Date of R& I & fee	Dy. No 13711 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Anti-diabetic/ hypoglycemic agents.
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	10's, 20's, 60's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Janumet Tablets by Merck (TGA approved)
	Me-too status	Tagipmet XR by M/s Highnoon Labs. (Reg.# 084650)
	GMP status	07.12.2017 Very good level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's Specifications.	

629.	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	Emitant 40mg Capsule
	Composition	"Each Capsule Contains: Aprepitant……..40mg"
	Diary No. Date of R& I & fee	Dy. No 14266 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-emetic
	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.	Emend (USFDA Approved)
	Me-too status	Apritus 40mg Capsule Of M/S S.J&G Reg. No. 74885.
	GMP status	12.07.2017 Good compliance level of GMP. GMP certificate issued.
	Remarks of the Evaluator	
	Decision: Approved.	
630.	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	Emitant 80mg Capsule
	Composition	"Each Capsule Contains: Aprepitant……..80mg"
	Diary No. Date of R& I & fee	Dy. No 14267 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-emetic
	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.	Emend (USFDA Approved)
	Me-too status	Apritus 80mg Capsule Of M/s S.J&G. Reg. No. 74886.
	GMP status	12.07.2017 Good compliance level of GMP. GMP certificate issued.
	Remarks of the Evaluator	
	Decision: Approved.	
631.	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	Emitant 125mg Capsule
	Composition	"Each Capsule Contains: Aprepitant……..125mg"
	Diary No. Date of R& I & fee	Dy. No 14268 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Anti-emetic
	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.	Emend (USFDA Approved)
	Me-too status	Apritus 80mg Capsule Of M/s S.J&G. Reg. No. 74886.
	GMP status	12.07.2017 Good compliance level of GMP. certificate issued.
	Remarks of the Evaluator	
	Decision: Approved.	
632.	Name and address of manufacturer / Applicant	"M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan."
	Brand Name +Dosage Form + Strength	Anomed 4mg/2ml Injection
	Composition	"Each 2ml Ampoule Contains: Ondansetron as Ondansetron hydrochloride……..4mg"

	Diary No. Date of R& I & fee	Dy. No 13707 dated 12-04-2018 Rs.20,000/- Dated 28-02-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed Manufacturer specification.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 2 Mg/Ml Solution For Injection (MHRA Approved).
	Me-too status	Adosetron 4mg Injection by M/s Searl IV Solutions Pakistan Reg. No. 78780.
	GMP status	13-09-2017 Purpose: GMP Compliance Conclusion: Satisfactory
	Remarks of the Evaluator	The firm applied for 3 products and attached 2 deposit slips of 50,000 and 10,000 separately for 3 products. Among 3 products one product named as Nitron Tablet has already been approved in DRB meeting 283rd. Deposit slips were overwritten by another product and firm was asked to clarify. Firm in response replied that "It was just because of wrong sentence written, that was corrected by overwriting and further verified by statistical officer DRAP."
	Decision: Approved with Innovator's specifications. Deposit slip shall be verified from Budget and Account Division before issuance of Registration letter.	
633.	Name and address of manufacturer / Applicant	"M/s Allmed Pvt Ltd. Plot No. 590, Sundar Industrial Estate, Lahore, Pakistan."
	Brand Name +Dosage Form + Strength	Anomed 4mg/5ml Oral Solution
	Composition	"Each 5ml Contains: Ondansetron Ondansetron as Ondansetron hydrochloride ……..4mg"
	Diary No. Date of R& I & fee	Dy. No 13708 dated 12-04-2018 Rs.20,000/- Dated 28-02-2018
	Pharmacological Group	Anti-Emetic Serotonin (5HT3) Antagonist.
	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.	Ondensetron oral solution by West-Ward Pharma (USFDA Approved).
	Me-too status	Ondanles by NeoMedics Pharma
	GMP status	13-09-2017 Purpose: GMP Compliance Conclusion: Satisfactory
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. Deposit slip shall be verified from Budget and Account Division before issuance of Registration letter.	
634.	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	Dexcin Cream
	Composition	"Each gram Contains: Dexamethasone Phosphate (As dexamethasone Phosphate)....1mg Neomycin……..3.5mg"
	Diary No. Date of R& I & fee	Dy. No 14092 dated 16-04-2018 Rs.20,000/- Dated 10-04-2018
	Pharmacological Group	Antibiotic, Corticosteroids.
	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.	No evidence could be verified from reference agencies.
	Me-too status	Me-too evidence could not be verified from available database.
	GMP status	11.10.2017 & 16.10.2017 Satisfactory level of GMP compliance.

	Remarks of the Evaluator	Submit international availability with same strength from reference countries agencies. Submit Me-too evidence with same strength with documentary proof.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
635.	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	Duphil 400mg Tablet
	Composition	"Each Tablet Contains: Doxyfylline……400mg"
	Diary No. Date of R& I &fee	Dy. No 13716 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Anti-Asthmatic
	Type of Form	Form-5
	Finished Product Specification	USP Specs
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Doxofillina ABC 400 Mg Tablet Of (AIFA Italy Approved).
	Me-too status	Unifyline 400mg Tablets Of M/S Platinum Pharma Reg. No. 47179
	GMP status	05.12.2017 Renewal of DML. Satisfactory level of GMP.
	Remarks of the Evaluator	
	Decision: Approved.	
636.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatabad."
	Brand Name +Dosage Form + Strength	Pericon 50mg Tablets
	Composition	"Each film coated tablet contains: Eperisone Hydrochloride……..50mg"
	Diary No. Date of R& I & fee	Dy. No 14259 dated 17-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	02×10's; 03×10'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	Perispa 50 Mg Tablets by Platinum Pharma (Reg# 039302)
	GMP status	Routine GMP inspection was conducted on 26.07.2017. Satisfactory level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
637.	Name and address of manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan."
	Brand Name +Dosage Form + Strength	Vomifit 10/10 mg Tablet
	Composition	"Each Delayed Release Capsule Contains: Doxylamine Succinate……10mg Pyridoxine HCl……10mg"
	Diary No. Date of R& I & fee	Dy. No 14346 dated 17-04-2018 Rs.20,000/- Dated 16-04-2018
	Pharmacological Group	Doxylamine, combinations
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	10's, 20's, 30's. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Diclegis delayed release tablets. US-FDA approved

	Me-too status	Nausidox 10mg/10mg Tablet. Reg. No. 76292
	GMP status	19.07.2017. Routine GMP inspection. Satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications and change of brand name.	
638.	Name and address of manufacturer / Applicant	"M/s CCL Pharmaceuticals (Pvt.) Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore."
	Brand Name +Dosage Form + Strength	Snare 2gm IV Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium eq. to ceftriaxone……2gm"
	Diary No. Date of R& I & fee	Dy. No 14478 dated 18-04-2018 Rs.20,000/- Dated 17-04-2018
	Pharmacological Group	Third generation cephalosporin antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1×1. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Rocephin (IV/IM) Injection 2gm By M/s Roche ProductsLimited (MHRA approved).
	Me-too status	Triax 2gm Injection of M/s. Wilshire Laboratories
	GMP status	08.03.2017 & 31.03.2017 GMP report conclusion not available.
	Remarks of the Evaluator	
	Decision: Approved.	
639.	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	Decon 50mcg/actuation Nasal Spray
	Composition	"Each actuation Contains: Mometasone Furoate Monohydrate Eq. to Mometasone Fumarate……50mcg"
	Diary No. Date of R& I & fee	Dy. No 13997 dated 13-04-2018 Rs.20,000/- Dated 11-04-2018
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer's specification
	Pack size & Demanded Price	Anti-allergic
	Approval status of product in Reference Regulatory Authorities.	Nasonex® 50 micrograms/actuation Nasal spray, suspension. MHRA approved.
	Me-too status	Hivate Nasal Spray By M/s Saffron Pharma Reg. No. 60352
	GMP status	16.02.2018. Satisfactory level of compliance.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility.	
640.	Name and address of manufacturer / Applicant	"M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad By M/s Vision Pharmaceuticals. Plot#22,23, Industrial Triangle, Kahuta Road, Islamabad."
	Brand Name +Dosage Form + Strength	Omitid 40mg IV Injection
	Composition	"Each Vial Contains: Omeprazole as Sodium…40mg"
	Diary No. Date of R& I & fee	Dy. No 13987 dated 13-04-2018 Rs.50,000/- Dated 13-04-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	As per SRO. 1's.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Risek 40mg Infusion by Getz Pharma Reg. No. 24170.
	GMP status	Panel Inspection of Applicant:

		M/s Siam, Pharma: - 16.02.2018. Recommended grant of renewal of DML. Panel Inspection of Manufacturer: M/s Vision Pharma. 26.01.2018. Good level of compliance. GMP certificate granted.
	Remarks of the Evaluator	The firm has provided list of already approved products registered for contract manufacturing i.e. 05 products and applied products for contract manufacturing are 05. The firm submitted that they have 02 approved sections.
	Decision: Approved with Innovator's specifications.	
641.	Name and address of manufacturer / Applicant	"M/s Siam Pharmaceuticals. 217, Industrial Triangle, Kahuta Road, Islamabad By M/s Vision Pharmaceuticals. Plot # 22, 23, Industrial Triangle, Kahuta Road, Islamabad."
	Brand Name +Dosage Form + Strength	Esiam 40mg IV Injection
	Composition	"Each Vial Contains: Esomeprazole as Sodium……..40mg"
	Diary No. Date of R& I & fee	Dy. No 13988 dated 13-04-2018 Rs.50,000/- Dated 13-04-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	As per SRO. 1's.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	Nexum IV 40mg Injection by Getz Pharma Reg. No. 50651.
	GMP status	As recorded for above application
	Remarks of the Evaluator	The firm has provided list of already approved products registered for contract manufacturing i.e. 05 products and applied products for contract manufacturing are 05. The firm submitted that they have 02 approved sections.
	Decision: Approved with Innovator's specifications.	
642.	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	Nebilol 5mg Tablet
	Composition	"Each Tablet Contains: Nebivolol as HCL…….5mg"
	Diary No. Date of R& I & fee	Dy. No 13873 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Beta Blockers
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer's specification.
	Pack size & Demanded Price	10s, 14s, 20s, 28s, 30s. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Nebix Tablets of M/s. Highnoon Laboratories (Reg.#062777).
	GMP status	24-04-2018. Satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)."
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
643.	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	Sipro XR 500mg Tablet
	Composition	"Each Tablet Contains: Ciprofloxacin as HCL…….500mg"
	Diary No. Date of R& I & fee	Dy. No 13874 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Fluoroquinolones

	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	5’s, 10’s, 14’s, 20’s. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Ciprofloxacin 500 mg TabletsBy DR REDDYS LABS LTD. US FDA Approved.
	Me-too status	Ciprin XR Tablets 500 mg by M/s Werrick Pharmaceuticals (Reg#044686).
	GMP status	As recorded for above application
	Remarks of the Evaluator	The applied product is not as per reference product.
	Decision: Deferred for revision of formulation as per US FDA approved reference product, since the reference product is Bi-layered tablet, while firm has applied for single layered tablet. Furthermore evidence of belayed tablet machine is also required to be submitted.	
644.	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 150/12.5 mg Tablet
	Composition	"Each Film coated Tablet Contains: Irbesartan…….150mg Hydrochlorothiazide……12.5mg"
	Diary No. Date of R& I & fee	Dy. No 13876 dated 13-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Angiotensin receptor blockers/diuretics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	5’s, 10’s, 14’s, 20’s. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Avalide tablet of Sanofi Aventis, USFDA approved.
	Me-too status	COAPROVEL tablet of Sanofi Aventis Reg. No. 043095.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
645.	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	Metrol 50mg Tablet
	Composition	"Each Tablet Contains: Metoprolol Tartrate……..50mg"
	Diary No. Date of R& I & fee	Dy. No 13875 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Beta Blocker
	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.	Lopressor Tablets 50mg by M/s Novartis, FDA approved.
	Me-too status	Carsel Tablets 50mg by M/s Lahore Chemical and Pharmaceuticals Reg. No. 24369.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
646.	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	Metrol 100mg Tablet
	Composition	"Each Tablet Contains: Metoprolol Tartrate…….100mg"
	Diary No. Date of R& I &fee	Dy. No 13878 dated 12-04-2018 Rs.20,000/- Dated 12-04-2018
	Pharmacological Group	Antihypertensive
	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.	Metoprolol tartrate 100mg of Milpharm, MHRA Approved.
	Me-too status	Carsel Plus 100mg tablet of M/s Unimark pharmaceuticals Reg. No. 38008
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	

Case No. 02: Registration Applications of Newly Granted DML or New Section (Human)

a. New/Additional Section(s)

01Molecule/02 Products		
647.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories, 124/A, Kotlakhpat, Indus: Area, Township scheme, Lahore.
	Brand Name +Dosage Form + Strength	Zune Insta 20mg Sachet
	Composition	Each Sachet contains: Esomeprazole enteric coated pellets 22.5% w/w.....20mg
	Diary No. Date of R& I & fee	Dy. No. 1326, 20-07-2018; Fee in PKR: 100,000/-17-07-2018.
	Pharmacological Group	Anti-ulcerative.
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's / As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Somezol by Bosch Pharma Karachi. (Reg. # 081611).
	GMP status	Date of Inspection: 27-08-18, 05-10-18, 06-11-18. Recommendations: The firm Wilshire Labs Lahore evaluated with respect to productions operations, personal, documentations, Quality assurance and quality control etc. Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections.
	Remarks of the Evaluator	Source of pellets: PRECISE CHEMIPHARMA PRIVATE LIMITED (710550), GUT NO. 215/1 & 215/2, KHATWAD PHATA, ATPOST-TALEGAON, TAL-DINDORI, DIST. NASHIK-422202, MAHARASHTRA, INDIA. Firm Submitted: - 1. GMP Certificate (Valid upto 27-02-2022). 2. CoAs. 3. Stability studies of three batches for 36 months of real time.
	Decision: Approved.	
648.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories, 124/A, Kotlakhpat, Indus: Area, Township scheme, Lahore.
	Brand Name +Dosage Form + Strength	Zune Insta 20mg Sachet
	Composition	Each Sachet contains: Esomeprazole enteric coated pellets 22.5% w/w.....20mg
	Diary No. Date of R& I & fee	Dy. No. 1326, 20-07-2018; Fee in PKR: 100,000/-17-07-2018.
	Pharmacological Group	Anti-ulcerative.
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specifications.
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's, 40's / As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Somezol by Bosch Pharma Karachi. (Reg. # 081611).
	GMP status	As recorded for above application

	Remarks of the Evaluator	Source of pellets: PRECISE CHEMIPHARMA PRIVATE LIMITED (710550), GUT NO. 215/1 & 215/2, KHATWAD PHATA, ATPOST-TALEGAON, TAL-DINDORI, DIST. NASHIK-422202, MAHARASHTRA, INDIA. Firm Submitted: - 1. GMP Certificate (Valid upto 27-02-2022). 2. COAs. 3. Stability studies of three batches for 36 months of real time.
	Decision: Approved.	

b. <u>New DML:</u>

Following registration dossiers have been received dated 07/03/ 2019 stating that the firm has been granted approval of new DML by way of formulation by Central Licensing Board in its 269th meeting for following thirteen (13) sections.

1. Tablet section (General)
2. Capsule section (General)
3. Cream/Ointment/Gel section
4. Oral liquid syrup section (General)
5. Dry powder oral suspension section (General)
6. Liquid Sterile Ampoule section (General)
7. Liquid Sterile Ampoule section (psychotropic)
8. Tablet section (psychotropic)
9. Sterile Ampoule section (steroid)
10. Sterile infusion/small volume vial section (General)
11. *Dry Powder for Injection (*Cephalosporin*)*
12. Capsule section (Cephalosporin)
13. Dry powder oral suspension section (Cephalosporin)

The following applications have been evaluated and presented before the Board.

S.No.	Section	No. of Products	No. of Molecules
1	Dry Powder for Injection (Cephalosporin)	15	5
2	Dry powder oral suspension section (Cephalosporin)	9	5
3	Capsule section (Cephalosporin)	6	4
4	Sterile infusion/small volume vial section (General	8	8
5	Liquid Sterile Ampoule section (General)	12	10

Dry Powder for Injection (Cephalosporin)05 Molecules/15 Products

649.	Name and address of manufacturer /Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Iqupam 500mg IV Injection
	Composition	"Each Vial Contains: Cefepime HCL with L-Arginine Eq. to Cefepime…….500mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15650 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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	Novapime injection 500mg of M/s Novamed Pharmaceuticals.

		Reg. No. 59905
	GMP Status	19.02.2019. Panel inspection for the purpose of grant of DML. Panel recommended for grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
656.	Name and address of manufacturer /Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Iqupam 1GM IV Injection
	Composition	"Each Vial Contains: Cefepime HCL with L-Arginine Eq. to Cefepime……..1000mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15651 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Maxipime 1gm of Hospira Inc., USA (USFDA).
	Me-too Status	Novapime Injection 1gm of M/s Novamed Pharmaceuticals. Reg. No. 59906.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
657.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Trix 250mg IM Injection
	Composition	"Each Vial Contains: Ceftriaxone as Ceftriaxone sodium…250mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15641 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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. USFDA approved.
	Me-too Status	Unixone Injection (ceftriaxone Sodium) 250mg IM by Caliph Pharmaceuticals (Pvt.) Ltd. Reg. No. 82556
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
658.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Trix 250mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone as Ceftriaxone Sodium…….250mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15637 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too Status	Stracef 250mg I.V. M/s Swiss Pharma Karachi. Reg. No. 42467

	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
659.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Trix 500mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone as Ceftriaxone Sodium…….500mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15638 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too Status	Rocephin Roche 500mg IV INJ By M/s Roche Pharma Karachi. Reg. No. 8435.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
660.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Trix 500mg IM Injection
	Composition	"Each Vial Contains: Ceftriaxone as Ceftriaxone Sodium…….500mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15642 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Rocephin powder for solution for injection by Roche (MHRA Approved).
	Me-too Status	Rocephin Roche 500mg IM INJ By M/s Roche Pharma Karachi. Reg. No. 8434
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
661.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Trix 1g IV Injection
	Composition	"Each Vial Contains: Ceftriaxone as Ceftriaxone Sodium…….1000mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15645 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Rocephin powder for solution for injection by Roche (MHRA Approved).
	Me-too Status	Rocephin Roche 1000mg IV INJ By M/s Roche Pharma Karachi. Reg. No. 8437
	GMP Status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Approved.	
662.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Trix 2g IV Injection
	Composition	"Each Vial Contains: Ceftriaxone as Ceftriaxone Sodium…….2000mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15640 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Rocephin IV Injection 2gm By M/s Roche Products Limited (MHRA approved).
	Me-too Status	Titan 2gm IV Injection by M/S Macter Pharma (Reg. No. 075825)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
663.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Tox 250mg IV Injection
	Composition	"Each Vial Contains: Cefotaxime as Sodium……..250mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15643 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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 Injection 250mg by M/s Amarant Pharmaceuticals Reg. No. 80277
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
664.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Tox 500mg IV Injection
	Composition	"Each Vial Contains: Cefotaxime as Sodium…500mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15644 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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 Injection 500mg by M/s Amarant Pharma R.No. 80278
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	

665.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Tox 1000mg IV Injection
	Composition	"Each Vial Contains: Cefotaxime as Sodium……..1gm"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15639 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
666.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Forfo 500mg IV Injection
	Composition	"Each Vial Contains: Ceftazidime as Pentahydrate…….500mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15648 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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	Vegazid 500mg Injection of Vega Pharmaceuticals.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
667.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Forfo 1000mg IV Injection
	Composition	"Each Vial Contains: Ceftazidime as Pentahydrate…1gm"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15649 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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	Panacef Injection 1gm by M/s CCL (Reg. No. 023986)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
668.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Sul-Fort 1000mg IV/IM Injection

	Composition	"Each Vial Contains: Cefoperzone as Sodium…500mg Sulbactam as Sodium…500mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15646 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Approved by PMDA-Japan
	Me-too Status	Cebac Injection 1gm by M/s Bosch (Reg#037630))
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with JP specifications.	
669.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Sul-Forte 2g IV Injection
	Composition	"Each Vial Contains: Cefoperazone as Sodium……..1000mg Sulbactam as Sodium……1000mg"
	Diary No. Date of R & I & Fee	Form-5 Dy. No 15647 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	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	Sulzone 2gm Injection by M/s Biocare Pharmaceuticals (Reg. No. 028469).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with JP specifications.	
	Dry powder oral suspension section (Cephalosporin) 05 Molecules/09 Products	
670.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Saclo 125mg/5ml Dry Powder Suspension
	Composition	"Each 5ml of Suspension Contains: Cefaclor as Monohydrate……..125mg"
	Diary No. Date of R & I & Fee	Dy. No 15633 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Cefaclor 125mg/5ml of (MHRA approved).
	Me-too Status	Sac-Lor 125mg/5ml Dry Powder Suspension of M/s Semos Pharma. Reg. No. 81617.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
671.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Saclo 250mg/5ml Dry Powder Suspension

	Composition	"Each 5ml of Suspension Contains: Cefeclor as Monohydrate…….250mg"
	Diary No. Date of R & I & Fee	Dy. No 15634 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Cefaclor 250mg/5ml powder for oral suspension of MHRA approved
	Me-too Status	Sac-Lor 250mg/5ml Dry Powder Suspension of M/s Semos Pharma. Reg. No. 81618.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
672.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Pod 50mg/5ml Dry Powder Suspension
	Composition	"Each 5ml of Suspension Contains: Cefpodoxime as Proxetil……..50mg"
	Diary No. Date of R & I & Fee	Dy. No 15635 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Cefpodoxime proxetil 50mg / 5 ml powder for oral suspension of USFDA approved.
	Me-too Status	Qink Dry Suspension 50mg/5ml of M/s Wilshire Laboratories Lahore Reg. No. 60519.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
673.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	C-Pod 100mg/5ml Dry Powder Suspension
	Composition	"Each 5ml of Suspension Contains: Cefpodoxime as Proxetil…100mg"
	Diary No. Date of R & I & Fee	Dy. 58hyNo 15636 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Cefpodoxime proxetil 100mg / 5 ml powder for oral suspension of USFDA approved.
	Me-too Status	Qink Dry Suspension 100mg/5ml of M/s Wilshire Laboratories Lahore Reg. No. 53636
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
674.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Fedric 125mg/5ml Dry Suspension

	Composition	"Each 5ml of Suspension Contains: Cefadroxil as Monohydrate…….125mg"
	Diary No. Date of R & I & Fee	Dy. No 15629 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	ORACEFAL powder for oral suspension (ANSM Approved)
	Me-too Status	Evacef Suspension 125mg/5ml of M/s Highnoon Laboratories Reg. No. 11213
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
675.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Fedric 250mg/5ml Dry Powder Suspension
	Composition	"Each 5ml of Suspension Contains: Cefadroxil as Monohydrate……250mg"
	Diary No. Date of R & I & Fee	Dy. No 15630 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Cefadroxil 250mg/5ml of (USFDA approved).
	Me-too Status	Evacef Suspension 250mg/5ml of M/s Highnoon Laboratories Reg. No. 11214.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
676.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Ziq 100mg/5ml Dry Suspension
	Composition	"Each 5ml of Suspension Contains:- Cefixime as Trihydrate……..100mg"
	Diary No. Date of R & I & Fee	Dy. No 15627 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Third generation cephalosporin antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	Suprax of Sanofi Aventis, USFDA
	Me-too Status	Cefim suspension of M/s Hilton Pharma (Reg. No. 022108).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
677.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Ziq 200mg/5ml Dry Suspension
	Composition	"Each 5ml of Suspension Contains: Cefixime as Trihydrate…….200mg"
	Diary No. Date of R & I & Fee	Dy. No 15628 dated 07-03-2019

		Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Third generation cephalosporin antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too Status	Cefim-Ds suspension of M/s Hilton Pharma (Reg.# 029082).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
678.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Rediq 250mg/5ml Dry Powder Suspension
	Composition	"Each 5ml of Reconstituted Suspension Contains: Cephradine as Monohydrate…250mg/5ml"
	Diary No. Date of R & I & Fee	Dy. No 15632 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	Approved in MHRA(Powder for Syrup).
	Me-too Status	Apacef 250 mg/5ml Dry Powder Suspension of ApexPharma Pharma Reg. No. 73542
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
Capsule section (Cephalosporin) 04 Molecules/ 06 products		
679.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Ziq 400mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Cefixime as Trihydrate……..400mg"
	Diary No. Date of R & I & Fee	Dy. No 15621 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	Suprax 400mg capsule of Sanofi Aventis, USFDA
	Me-too Status	Cefiget capsule 400mg of GETZ Pharma
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with JP specifications.	
680.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Fedric 500mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Cefadroxil as Monohydrate……..500mg"
	Diary No. Date of R & I & Fee	Dy. No 15622 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019

	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	Cefadroxil 500 mg capsules, hard (containing Cefadroxil as monohydrate 500 mg) by Sandoz Ltd. Approved by MHRA.
	Me-too Status	Galen 500mg Capsule by Ankaz Pharma Karachi. Reg. No. 70647
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
681.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Rediq 250mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains:- Cephradine monohydrate eq. to Cephradine……250mg"
	Diary No. Date of R & I & Fee	Dy. No 15623 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	Cephradine 250mg Capsule by TEVA PHARMA USA (USFDA)
	Me-too Status	Zasinol 250mg Capsule (080643)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
682.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Rediq 500mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Cephradine Monohydrate eq. to Cephradine ……500mg"
	Diary No. Date of R & I & Fee	Dy. No 15624 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As pee SRO
	Approval Status of product in Reference Regulatory Authorities	Cephradine 500mg Capsule by TEVA PHARMA USA (USFDA)
	Me-too Status	Zasinol 250mg Capsule (080644)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
683.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Saclo 250mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Cefeclor as Monohydrate…….250mg"
	Diary No. Date of R & I & Fee	Dy.#15625 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Second-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	Cefaclor Capsules 250mg (Cefaclor monohydrate Ph Eur Eq. to 250mg of Cefaclor) by Strides Pharma UK Ltd. Approved by MHRA.
	Me-too Status	Deduclol 250mg Capsule by Martin Dow Karachi. R.# 80640
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
684.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Saclo 500mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Cefeclor as Monohydrate……..500mg"
	Diary No. Date of R & I & Fee	Dy. No 15626 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Second-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	Cefaclor Capsules 500mg (Cefaclor monohydrate Eq. to 500mg of Cefaclor) by Kosei Pharma UK Limited. Approved by MHRA
	Me-too Status	Deduclol 500mg Capsule by Martin Dow Karachi. R.# 80639
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
	Sterile infusion/small volume vial section (General) 08 Molecules/ 08 Products.	
685.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Linca 600mg/2ml Ampoule
	Composition	"Each 2ml Vial Contains: Lincomycin Hydrochloride Monohydrate Eq. to Lincomycin…600mg"
	Diary No. Date of R & I & Fee	Dy. No 15527 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antibiotic,
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	LINCOCIN 600mg/2ml (Vial) solution for injection by M/s Pharmacia and Upjohn (USFDA Approved).
	Me-too Status	Dds Lincomycin 600mg Injection by M/s Global Pharma, Reg. No. 32155
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility for 2ml vial.	
686.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Oflix 200 mg / 100ml Injection
	Composition	"Each 100ml Injection Contains: Ofloxacin ……. 200mg"
	Diary No. Date of R & I & Fee	Dy. No 15533 dated 07-03-2019

		Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's spec.
	Pack Size & Demanded Price	01×100ml. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Tarivid Infusion 2mg/ml (MHRA approved)
	Me-too Status	Anacaine Injection by M/s Akson Pharma. (Reg.# 037614)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with Innovator's specifications.	
687.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Imidol 5mg/ml IV Infusion
	Composition	"Each 100ml infusion Contains: Metronidazole…….500mg"
	Diary No. Date of R & I & Fee	Dy. No 15534 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-amoebic
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	100ml. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Metronidazole Infusion (MHRA Approved)
	Me-too Status	Resgyl Infusion 500 mg / 100 ml by M/s Rasco Pharma
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with BP specifications.	
688.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Roxil 2mg / ml Intravenous Infusion
	Composition	"Each 100ml Infusion Bottle Contains: Ciprofloxacin lactate eq. to ciprofloxacin ……. 200mg"
	Diary No. Date of R & I & Fee	Dy. No 15509 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
689.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	I-Quin 5mg /ml Intravenous Infusion
	Composition	"Each 100ml Infusion Bottle Contains: Levofloxacin Hemihydrate eq. to Levefloxacin ……. 500mg"
	Diary No. Date of R & I & Fee	Dy. No 15522 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Fluoroquinolone

	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	1 x 100ml: As per SRO
	Approval Status of product in Reference Regulatory Authorities	Levofloxacin solution for infusion 500mg/100ml (Vial) by Hikma Farmacêutica (Portugal), S.A (MHRA Approved).
	Me-too Status	Levaquin 500mg I.V Injection by Barrett Hodgson Reg.# 023875
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with JP specifications.	
690.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Avelux 1.6mg/ml Intravenous Infusion
	Composition	"Each 100ml Infusion Bottle Contains: Moxifloxacin as Hcl……160mg"
	Diary No. Date of R & I & Fee	Dy. No 15510 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's spec.
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Avelox 400mg/250ml by Bayer Pharma. MHRA Approved. International availability from reference countries agencies with applied strength and pack size could not be verified.
	Me-too Status	Cinmox Infusion 1.6mg by M/s nexus Pharma Reg. No. 61596
	GMP Status	As recorded for above application
	Remarks of the Evaluator	International availability from same reference countries agencies with applied strength and pack size could not be verified.
	Decision: Deferred for following: **International availability from reference countries agencies with applied strength and pack size could not be verified.**	
691.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	P-Mol 10mg/ml Intravenous Infusion
	Composition	"Each 100ml Infusion Bottle Contains: Paracetamol……1000mg"
	Diary No. Date of R & I & Fee	Dy. No 15532 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	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	Perfalgan 10mg/ml, solution for infusion (MHRA approved).
	Me-too Status	Provas Infusion 10mg/ml of M/s Sami Pharma Reg. No. 53223
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
692.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Gentle 80mg/2ml Injection
	Composition	"Each 2ml Glass Vial Contains: Gentamicin Sulphate……80mg"
	Diary No. Date of R & I & Fee	Dy.#15530 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Gentamicin Injection by M/s Fresenius Kabi USA, LLC
	Me-too Status	Genta Injections by m/s Epoch Pharma Reg. No. 47130
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility for 2ml vial.	
Liquid Sterile Ampoule section (General) 10Molecules/12 Products		
693.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Ayanol 5mg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Cholecalciferol……..5mg"
	Diary No. Date of R & I & Fee	Dy. No 15592 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Vitamin D
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	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	Calciferol Injection M/s Global Pharmaceuticals.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
694.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Water for Injection 5ml
	Composition	"Each 5ml Ampoule Contains: Sterile Water for Injection…….5ml"
	Diary No. Date of R & I & Fee	Dy.#15595 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Diluent/Solvent
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5ml ×10 Ampoule, 5ml ×100 Ampoule, 5ml ×1000 Ampoule. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too Status	Aqua R ampoule by M/s Regal Pharmaceuticals (Reg#082010).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
695.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Water for Injection 10ml
	Composition	"Each 10ml Ampoule Contains: Sterile Water for Injection……10ml"

	Diary No. Date of R & I & Fee	Dy. No 15521 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Diluent/Solvent
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10ml ×10 Ampoule, 10ml ×100 Ampoule, 10ml ×1000 Ampoule. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too Status	Water for injection 10ml by M/s Novamed (Reg#076972)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
696.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Nevitra 500mg/5ml Injection
	Composition	"Each 5ml Ampoule Contains: Levetiracetam…….500mg"
	Diary No. Date of R & I & Fee	Dy. No 15528 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's & 10's. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	USFDA approved
	Me-too Status	Eplipsa 500mg/5ml Injection of M/s Helix (Reg.#075918)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
697.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Katro 30mg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Ketorolac Tromethamine……..30mg"
	Diary No. Date of R & I & Fee	Dy. No 15594 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Analgesic, anti-inflammatory
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	02x05 ampoules, 50 ampoules & 100 ampoules. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Toradol Injection of Atnahs Pharma, UK (MHRA Approved)
	Me-too Status	Toralac Injection 30mg/ml by M/s Vision Pharma (Reg#050290).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
698.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Mevit 500mcg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Mecobalamin……..500mcg"

	Diary No. Date of R & I & Fee	Dy. No 15591 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	02x05 ampoules, 50 ampoules & 100 ampoules. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	PMDA approved.
	Me-too Status	Wycomin 500 mcg Injection by Wnsfeild Pharmaceuticals. Reg. No. 75581.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
699.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Diqran 75mg/3ml Injection
	Composition	"Each 3ml Ampoule Contains: Diclofenac Sodium……75mg"
	Diary No. Date of R & I & Fee	Dy. No 15583 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	NSAID's.
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x5ampoules, 25 ampoules & 100ampoules. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Voltarol ampoules 75mg/3ml (UK-MHRA).
	Me-too Status	Defnac 75mg/3ml of M/s Searle Pakistan Pvt. Ltd.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
700.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	I-Spa 40mg/2ml Injection
	Composition	"Each 2ml Ampoule Contains: Drotaverine as HCl…….40mg"
	Diary No. Date of R & I & Fee	Dy. No 15531 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Anti-spasmodic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) (Link: https://www.ogyei.gov.hu/gyogyszeradatbazis/index.php?action=show_details&item=11235) 2. 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) (Link: https://www.anm.ro/_/_RCP/RCP_6973_10.10.14.pdf
	Me-too Status	NO-SPA Injection of M/s Sanofi Aventis Pakistan R.No. 8296.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with Innovator's specifications.	

701.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Qinimide 20mg/2ml Injection
	Composition	"Each 2ml Ampoule Contains: Furosemide…….20mg"
	Diary No. Date of R & I & Fee	Dy. No 15524 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Loop Diuretics
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	2mlx50ampoules. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Furosemide 20mg /2ml solution for Injection (MHRA approved)
	Me-too Status	Lasix Injection of Sanofi Aventis (Reg#000230)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with JP specifications.	
702.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	RBC-Fer 100mg/5ml Injection
	Composition	"Each 5ml Ampoule Contains: Iron as Iron Sucrose…….100mg"
	Diary No. Date of R & I & Fee	Dy. No 15593 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Iron salt
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	1x5 ampoules. As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Venofer Injection by Vifor (MHRA Approved).
	Me-too Status	Vortex 100mg/ 5ml injection of Saturn Pharma Reg. No. 71281
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with BP specification and change of brand name.	
703.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Lidolic 10mg/ml injection
	Composition	"Each 2ml Ampoule Contains: Lidocaine Hcl……..20mg"
	Diary No. Date of R & I & Fee	Form-5 Dy.#15589 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Local anaesthetics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	01x5ampoules
	Approval Status of product in Reference Regulatory Authorities	Lidocaine injection 1% w/v of B. Braun (MHRA approved)
	Me-too Status	Lidocaine HCl 1% Injection of Healthtek (Reg#079939)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved as IM preparation.	
704.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Lidolic 20mg/ml Injection

	Composition	"Each 2ml Ampoule Contains: Lidocaine HCl……..40mg"
	Diary No. Date of R & I & Fee	Dy. No 15590 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Local anaesthetics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	02x5ampoules
	Approval Status of product in Reference Regulatory Authorities	Approved by MHRA of UK.
	Me-too Status	Lignox 2% injection (2ml) of M/s Novamed (Reg. #076968).
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved as IM preparation.	

Case No. 03: Registration Applications for Local Manufacturing of (Veterinary) Drugs.

a. New Cases:-

705.	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	Rafticol Liquid
	Composition	Each 100 ml contains: Florfenicol……..11gm Colistine Sulphate…….50MIU
	Diary No. Date of R& I & fee	Dy. No.11790; 30-03-2018; Rs.20,000/- (28-03-2018)
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1 Litre, 2.5 litre, 5Liter, 15 Litre, 20 Litre, 25 Litre. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	F-COL Liquid by "D-Maarson Pharmaceuticals, Plot # 17, Street SS-2, National Industrial Zone, Rawat, Islamabad." Reg. No. 072679.
	GMP status	Routine GMP inspection was conducted on 03.10.2018 by Area FID and concluded as under: The firm is considered to be operating at satisfactory level of GMP and found to be fulfilling GMP requirements.
	Remarks of the Evaluator	
	Decision:Approved with Innovator's specifications.	
706.	Name and address of manufacturer / Applicant	Farm Aid Group, plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Tylofag Powder
	Composition	"Each kg Contains:- Tylosin Tartrate ……...500gm"
	Diary No. Date of R& I & fee	Dy. No.11789; 30-03-2018; Rs.20,000/- (28-03-2018)
	Pharmacological Group	Macrolid Antibiotic
	Type of Form	Form5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1 kg, 5kg, 10kg, 15kg, 20kg, 25kg.
	Approval status of product in Reference Regulatory Authorities.	N/A

	Me-too status	Tylo-50 Water Soluble Powder by M/s Symans Pharmaceuticals (Pvt) Ltd, Lahore. Reg. No. 63847.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
707.	Name and address of manufacturer / Applicant	Farm Aid Group, plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	Doxy-DS Powder
	Composition	Doxycycline Hcl……....400gm Tylosin Tartrate……200gm Colistin Sulphate……500MIU Bromhexine Hcl……10gm
	Diary No. Date of R& I & fee	Dy. No.11791; 30-03-2018; Rs.20,000/- (28-03-2018)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1 kg, 5kg, 10kg, 15kg, 20kg, 25kg.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Fit Respi Water Soluble Powder by "D-Maarson Pharmaceuticals, Plot # 17, Street SS-2, National Industrial Zone, Rawat, Islamabad."
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
708.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur
	Brand Name +Dosage Form + Strength	Animec Injection
	Composition	Each ml contains: IVERMECTIN.....10.5mg.
	Diary No. Date of R& I & fee	Dy. No.828; 05-01-2018; Rs.20,000/- (22-12-2017)
	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	I-Mectin injection by M/s International Pharma Labs., Raiwind Road Lahore. Reg. No. 63618
	GMP status	Panel inspection was conducted on 13.09.2018 & 14.09.2018 for the purpose of renewal of DML and grant of additional section. The panel recommended renewal of DML and grant of additional sections.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
709.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tiamax Water Soluble Powder
	Composition	Each 100gm contains: Tiamulin (as Hydrogen Fumerate)……45gm
	Diary No. Date of R& I & fee	Dy. No.827; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Broad Spectrum Antibiotic

	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg, 10kg, Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Tiamubak 45% Oral Powder by M/s Attabak pharmaceuticals, Islamabad. Reg. No. 048170
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
710.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tilmax Oral Solution
	Composition	Each ml contains: Tilmicosin Phosphate……250mg
	Diary No. Date of R& I & fee	Dy. No.824; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Macrolid Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	240ml, 500ml, 1000ml, 5 Litre, Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Biotil Reg. No. 046568 by Bio-Labs (Pvt) Ltd., Islamabad.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
711.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Savizol Drench
	Composition	Each ml contains: Oxyclozanide…….22.65mg
	Diary No. Date of R& I & fee	Dy. No.815; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5 Litre, Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Me-too could not be confirmed from available database.
	GMP status	As recorded for above application
	Remarks of the Evaluator	Me-too could not be confirmed from available database.
	Decision: Deferred for providing evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
712.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Albazen Drench
	Composition	Each ml contains: Albendazole……...112.5mg
	Diary No. Date of R& I & fee	Dy. No.816; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5 Litre, Decontrolled.

	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Valbazen Drench 11.25% of SK & F (Reg. No. 013228)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
713.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Fluxin Injection
	Composition	Each ml contains: Flunixin Meglumine……..50mg
	Diary No. Date of R& I &fee	Dy. No.832; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Non-steroidal, Analgesic Agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml Glass vial, 20ml Glass vial, 50ml Glass vial, 100ml Glass vial.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Loxin Injection By M/S Selmore Pharmaceuticals (Pvt) Ltd, Lahore. Reg. No. 35098
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
714.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Trobanil R.T.U Injection
	Composition	Each ml contains: Diminzene Aceturate……50mg Antipyrine……350mg
	Diary No. Date of R& I & fee	Dy. No.830; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Anti-protozoan; Antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml Glass vial, 20ml Glass vial, 50ml Glass vial, 100ml Glass vial.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Fa Try Banil R.T.U. Injection by M/s prix Pharma. R.# 27476
	GMP status	As recorded for above application
	Remarks of the Evaluator	Me-too status of applied strength could not be verified from available database. Accordingly firm was asked to clarify. Firm in response submitted revised strength from 250mg to 350mg as per Me-too along with differential fee of Rs.5000/dated 08.05.2019 with deposit slip no. 1936659.
	Decision: Deferred for deliberation regarding chemical nature of Anti-pyrine.	
715.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Colimax Water Soluble Powder
	Composition	Each 100gm contains: Colistin Sulphate…….50MIU
	Diary No. Date of R& I & fee	Dy. No.821; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications

	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5kg
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Me-too status could not be verified from available database.
	GMP status	As recorded for above application
	Remarks of the Evaluator	Submit Me-too reference evidence. Submit Form-5 undertaking duly signed by concerned person.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
716.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Neofarm Water Soluble Powder
	Composition	Each gram contains: Neomycin Sulphate ……..700mg
	Diary No. Date of R& I & fee	Dy. No.818; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Antibiotic, Ant glycoside
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1kg, 5kg, 10kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Neocin Powder by M/s Leads Pharma (Pvt) Ltd., Islamabad. Reg. No. 063714
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
717.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tetragen Water Soluble Powder
	Composition	Each kg contains:- Tiamulin hydrogen Fumerate……124gm Chlortetracycline Hydrochloride……321.54gm
	Diary No. Date of R& I & fee	Dy. No.817; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Broad spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1kg, 5kg, 10kg
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	CDC Plus Water Soluble Powder by M/s Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi Reg. No. 49689
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
718.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Fighter Drench
	Composition	Each ml contains:- Oxyclozanide……62.5mg Oxfendazole……..22.5mg
	Diary No. Date of R& I & fee	Dy. No.813; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5 Litre
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Thunder Drench by Star Laboratories (Pvt) Ltd, Lahore, Reg. No. 58941
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
719.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Kilzan Drench
	Composition	Each ml contains:- Levamisole…….15mg Oxyclozanide……..30mg
	Diary No. Date of R& I & fee	Dy. No.874; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Anthelmintic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5 Litre
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	El-Levaclozanil Suspension by Elko Organization Karachi Reg. No. 022158
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
720.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Bromex Oral Solution
	Composition	Each ml contains:- Bromhexine HCl……..10mg Methanol……..20mg
	Diary No. Date of R& I & fee	Dy. No.825; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml, 500ml, 1000ml, 5 Litre
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Baxsel-E solution by M/s Baxter Pharmaceuticals, A-1/A, Scheme # 3, Phase 1, S.I.T.E., Super Highway, Karachi. Reg. No. 72636.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
721.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Diarin Oral Powder
	Composition	Each 28gm Contains:- Neomycin Sulphate…….0.538gm Streptomycin Sulphate……0.676gm Sulphaguandine……...5gm Phthalyl Sulphathiazole……...1.5gm

		Riboflavin……0.1gm Nicotinamid…….0.5gm
	Diary No. Date of R& I & fee	Dy. No. 826; 05-01-2018 Rs. 20,000/- (22-12-2017)
	Pharmacological Group	Combination of Antibiotics & Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	28gm, 100gm, 500gm, 1kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Neodiaristin Oral Powder by M/s Prix Pharmaceuticals, Lahore Reg. No. 33221
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
722.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Tamulin 125 Oral Solution
	Composition	Each ml Contains: Tiamulin Hydrogen Fumerate…125mg
	Diary No. Date of R& I & fee	Dy. No 823; 05-01-2018 Rs. 20,000/- (22-12-2017)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5 Litre.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Vetamulin-100 Injection. By M/s LabPak International (Pvt) Ltd., Islamabad Reg. No. 48143
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
723.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Roxaflox Gold Oral Soution
	Composition	Each ml Contains: Enrofloxacin Base…200mg
	Diary No. Date of R& I & fee	Dy. No.822; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml, 5 Litre
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Vety-Enrox Liquid by Vety-Care Islamabad Reg. No. 19940
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
724.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Mineral Injection
	Composition	Each ml Contains:- Sodium as Iodide……...50mg Potassium as Iodide.....50mg Potassium as Chloride.....4.28mg Zinc as Chloride.....0.135mg

		Manganese as Chloride.....0.885mg Magnesium as Chloride.....19.64mg Copper as Chloride.....0.220mg Ferrous as Chloride.....12.960mg Molybdenum as Ammonium Molybdate.....0.018mg Cobalt as Chloride.....0.164mg Calcium as Gluconate.....300mg
	Diary No. Date of R& I & fee	Dy. No.831; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Mineral Supplements
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml Glass Vial, 20ml Glass Vial, 30ml Glass Vial, 50ml Glass Vial, 100ml Glass Vial. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Minerasol Injection by Selmore Pharmaceuticals (Pvt) ltd., Lahore Reg. No. 29664.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
725.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	CRC 25 % Water Soluble Powder
	Composition	Each Gram Contains:- Chlortetracycline as HCl…….. 250mg.
	Diary No. Date of R& I & fee	Dy. No.819; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	500gm, 1kg, 5kg, 10kg, Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Chlortetravet Water Soluble Powder by M/s Samara Stores, Hyderabad Reg. No. 28567
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
726.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Micospec Injection
	Composition	Each ml Contains: Spectinomycin as HCL……100mg Lincomycin HCL……..50mg
	Diary No. Date of R& I & fee	Dy. No.829; 05-01-2018; Rs.20,000/- (22-12-2017)
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml Glass Vial, 20ml Glass Vial, 50ml Glass Vial, 100ml Glass Vial. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Lincopec Injection by M/s Leads Pharma. Reg. No. 043581
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. Firm shall select 01 fill volume of the product.	

727.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Hydromycin Water Soluble Powder
	Composition	Each kg Contains: Lincomycin as HCL…….400gm
	Diary No. Date of R& I & fee	Dy. No.13039; 06-04-2018; Rs.20,000/- (27-02-2018)
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1000gm, 5kg, 10kg, 20kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Lincocin 40% Soluble Powder by M/s Pharmacia Pakistan Pvt. Ltd., Islamabad Reg. No. 29685
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
728.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Duralin Complex Injection
	Composition	Each ml Contains: Oxytetracycline HCL……10mg Dexamethasone as Sodium Phosphate……..0.5mg
	Diary No. Date of R& I & fee	Dy. No 13038, dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Anti-Inflammatory-Anti biotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10 ml Clear Glass vial, 20 ml Clear Glass vial, 30 ml Clear Glass vial, 40 ml Clear Glass vial, 50 ml Clear Glass vial, Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	OXY COMPLEX INJECTION 150MG
	GMP status	As recorded for above application
	Remarks of the Evaluator	The Firm was asked to clarify Me-too and formulation, firm in reply submitted revised formulation from 100mg to 10mg as per Me-toowithout submission of fee.
	Decision: Deferred for submission of differential fee for revised formulation i.e. Rs.5000/=.	
729.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Rapidox Water Soluble Powder
	Composition	Each kg Contains: Doxycycline Hyclate……..400gm Tylosin Tartrate……..200gm
	Diary No. Date of R& I & fee	Dy. No 13037 dated 06-04-2018 Rs.20,000/- 27-02-2018
	Pharmacological Group	Broad Spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg, 10kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A

	Me-too status	Bax Tylo 60 Powder by M/s "Baxter Pharmaceuticals, Super Highway, Karachi Reg. No. 72640
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
730.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Hi-Renyl Powder
	Composition	Each 100gm Contains: Ammonium Chloride……45gm Magnesium Sulphate……25gm Sodium Sulphate……...25gm Sorbitol……..5gm
	Diary No. Date of R& I & fee	Dy. No 13036 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Nutritional Supplement (Dietary electrolyte balance)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1kg, 5kg, 10kg, 20kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Renal Plus Powder by M/s Bio-Labs Pvt. Ltd, Reg. No. 43173.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
731.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Vitamax K3 Water Soluble Powder
	Composition	Each kg Contains: Vitamin K3……..40gm
	Diary No. Date of R& I &fee	Dy. No 13035 dated 06-04-2018 Rs.20,000/- 27-02-2018
	Pharmacological Group	Vitamin Supplements
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg, 10kg, 20kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Me too status could not be verified from the available database.
	GMP status	As recorded for above application
	Remarks of the Evaluator	Me-too could not be verified from available database. Applied product is Vitamin K3 Powder and Attached deposit slip is for Spasmin Injection.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Deposit slip clarification.**	
732.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Curbex Powder
	Composition	Each kg Contains: Calcium Propionate……44.5% Sorbic Acid……..4% Fumaric Acid……4%

	Diary No. Date of R& I & fee	Dy. No 13024 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Calcium supplement
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1kg, 5kg, 10kg, 20kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Myco Curb Dry Powder by M/s Vet Pharma Trading Gujranwala Reg. No. 20145
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
733.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Salimax 120 Premix
	Composition	Each kg Contains: Salinomycin Sodium……120gm
	Diary No. Date of R& I & fee	Dy. No 13031 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1kg, 5kg, 10kg, 20kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Salinomix Water Soluble Powder 6% by M/s Rex Pharmaceutical Pakistan, Karachi.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Brand name "Salimax 120"and Innovator's specifications.	
734.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Lipodol Powder
	Composition	Each Kg Contains: Clopidol……..98%"
	Diary No. Date of R& I &fee	Dy. No 13030 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Antiprotozoal
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1kg, 5kg, 10kg, 20kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Clopidol Powder By M/S Vetimpex Trading Co Karachi Reg. No. 14516
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications.	
735.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Mycoban 200 Premix
	Composition	Each kg Contains: Monensin Sodium……200gm

	Diary No. Date of R& I & fee	Dy. No 13029 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Broad spectrum Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1kg, 5kg, 10kg, 20kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Elancoban 200 premix by M/s Eli Lilly Fegersheim Exp by Eli Lilly Switzerland Reg. No. 013729.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with the Brand name "Mycoban 200" and Innovator's specifications.	
736.	**Name and address of manufacturer / Applicant**	**MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.**
	Brand Name +Dosage Form + Strength	Grafix Plus Powder
	Composition	Each kg Contains: Inactivated Yeast……..31% Diatomaceous Earth……..55.2% Zeolite……...13%
	Diary No. Date of R& I & fee	Dy. No 13032 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Saccharomyces cerevisiae
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1kg, 5kg, 10kg, 20kg, 25kg. Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Mycofix Plus by M/s Naseem Vet Rawalpindi. Reg. No. 19910
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Registration Board decided to seek comments of H&OTC Division about formulation.	
737.	Name and address of manufacturer / Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Vita-3 Injection
	Composition	Each ml Contains: Vitamin A Palmitate……80,000 IU Vitamin E Acetate……...20mg Vitamin D3…….40,000 IU
	Diary No. Date of R& I & fee	Dy. No 13026 dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10 ml Clear Glass vial, 20 ml Clear Glass vial, 30 ml Clear Glass vial, 50 ml Clear Glass vial, 100 ml Clear Glass vial, Decontrolled.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Vitamin AD3E Injection by M/s Prix Pharma Reg. No. 22175

	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specifications. Firm shall select 1 fill volume of the product.	

Case No. 04: Registration Applications of Newly Granted DML or New Section (Veterinary)

a. New Section (New Cases)

Oral Powder Section 10 Molecules/ 22 Products.		
738.	Name and address of manufacturer /Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	ANTHEY PLUS POWDER
	Composition	Each 1000 gm Contains:- Levamisole HCL……750 gm
	Diary No. Date of R & I & Fee	Dy. No. 11632; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	Levoral 75% by N.B Sons (Pvt) Ltd., Lahore. (Reg. No. 049588)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with Innovator's specifications.	
739.	Name and address of manufacturer /Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	BROMODOX-60 POWDER
	Composition	Each 100 gm Contains :- Tylosin Tartrate…….20 gm Doxycycline Hyclate……40 gm Colistin Sulphate…….....10 gm Bromhexine HCL……..2 gm
	Diary No. Date of R & I & Fee	Dy. No. 11637; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	BROCOTYD by Univet Pharmaceuticals (Reg. No. 058962).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	Firm was asked to correct salt from Doxycycline HCL to Doxycycline Hyclate along with the submission of applicable fee. Firm in response submitted revised Form5 with correct label claim but did not submit the fee for revision of formulation.
	Decision:Deferred for submission of fee for revision of formulation.	
740.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	PARA-COOL POWDER
	Composition	Each 100 gm Contains :- Paracetamol……..20 gm

		Vitamin C……..5 gm Potassium Carbonate…….12.5 gm Sodium Bicarbonate……..12.5 gm Vitamin E……..1.25 gm
	Diary No. Date of R & I & Fee	Dy. No. 11636; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	PARACE by Biogen Pharmaceuticals (Reg. No. 063812)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	Firm was asked to correct API Strength in Master formulation as per Me-too or justify the formulation. Firm in reply submitted same formulation which is not as per Me-too.
	Decision:Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
741.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	LINCO FORTE-V POWDER
	Composition	Each 1000 gm Contains :- Lincomycin HCL……110 gm
	Diary No. Date of R & I & Fee	Dy No. 11649; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	Lincowan Forte by Nawan Labs Karachi. (Reg. No. 022149).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
742.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	ANTA 10 POWDER
	Composition	Each 100 gm Contains:- Amantadine HCL……10 gm
	Diary No. Date of R & I & Fee	Dy. No. 11652; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic/ Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	ACEDINE by Leads Pharmaceuticals (Reg. No. 078356)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	

743.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	SE-DOX 50 POWDER
	Composition	Each 1000 gm Contains:- Doxycycline HCL……500 gm
	Diary No. Date of R & I & Fee	Dy No. 11639; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Tetracycline
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	Me-too could not be verified from available data base.
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	Firm was asked to submit Me-too or correct salt from Doxycycline HCL to Doxycycline Hyclate as per available Me-too along with the submission of applicable fee. Firm in response submitted me-too which is Doxycycline Hyclate of M/s Selmore.
	Decision:Deferred for submission of fee for revision of formulation.	
744.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	SE- LINCO POWDER
	Composition	Each 1000 gm Contains :- Lincomycin HCL……..44 gm
	Diary No. Date of R & I & Fee	Dy. No. 11633; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	Lincomix Powder by Pfizer Animal Health (Reg. No. 017935).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
745.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	D-TYLOXINE 20 POWDER
	Composition	Each 1000 gm Contains :- Tylosin Tartrate……200 gm Doxycycline Hyclate……400 gm Colistin Sulphate……..1000 M.I.U Bromhexine HCL……10 gm
	Diary No. Date of R & I & Fee	Dy. No. 11629; 06-03-2019; Rs. 20,000/- (01.03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	MAKZIM PLUS by Evergreen Pharmaceuticals Reg.No.
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19

	Remarks of the Evaluator	Firm was asked to correct salt from Doxycycline HCL to Doxycycline Hyclate along with the submission of applicable fee. Firm in response submitted revised Form5 with correct label claim but did not submit the fee for revision of formulation.
	Decision:Deferred for submission of fee for revision of formulation.	
746.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	BROMODOX-30 POWDER
	Composition	Each 1000 gm Contains :- Tylosin Tartrate……100 gm Doxycycline HCL……200 gm Colistin Sulphate……..400 M.I.U Bromhexine HCL……3 gm
	Diary No. Date of R & I & Fee	Dy No. 11624; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	BROMODOX-T by Attabak Pharmaceuticals (Reg.No. 049788).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
747.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	OXINOTIN-V POWDER
	Composition	Each 1000 gm Contains:- Oxytetracycline HCL…….200 gm Neomycin Sulphate……200 gm Colistin Sulphate…….. …….240 M.I.U
	Diary No. Date of R & I & Fee	Dy. No. 11623; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	OXCINOCOL by Elegance Pharmaceuticals (Reg. No. 034533)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
748.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	LINCOMAX POWDER
	Composition	Each gm Contains :- Lincomycin as HCL……400 mg
	Diary No. Date of R & I & Fee	Dy No. 11620; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification

	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	LINCOSEL 40 by Selmore Pharmaceuticals (Reg No. 089826)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
749.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	FLORO –FORTE
	Composition	Each gm Contains:- Neomycin Sulphate……..150 mg Florfenicol……100 mg Oxytetracycline HCL……300 mg
	Diary No. Date of R & I & Fee	Dy. No. 11627; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	E-COL by Evergreen Pharmaceuticals (Reg. No. 081733)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	Firm was asked to Revise Oxytetracycline to Oxytetracycline HCL in label claim and Master Formula as per Me-too along with the submission of applicable fee. Firm submitted revised form5 with correct label claim and fee of Rs.5000/ deposit slip No. 0828982 dated 08/05/2019.
	Decision:Approved with innovator's specification.	
750.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	SE REST POWDER
	Composition	Each 1000 gm Contains :- Tylosin Tartarate……..200 gm Doxycycline HCL…….400 gm Colistin Sulphate……...500 M.I.U Bromhexine HCL……..10 gm
	Diary No. Date of R & I & Fee	Dy. No. 11638; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic/ Expectorant
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	DOX 40 by Nawal Pharmaceuticals (Reg. No. 074096).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification and change of brand name.	
751.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	COLIDOXIL –DS POWDER

	Composition	Each 100 gm Contains :- Tylosin Tartrate……20 gm Doxycycline HCL……40 gm Colistin Sulphate……6 gm Bromhexine HCL……2 gm
	Diary No. Date of R & I & Fee	Dy. No. 11621; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	NOBI TDC 680 by Noble Pharmaceuticals (Reg. No. 062127).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
752.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	BLSS 4 POWDER
	Composition	Each 100 gm Contains:- Lincomycin HCL……5 gm Spectinomycin HCL……7.5 gm Spiramycin Adipose……2.5 gm Bromhexine HCL……0.5 gm
	Diary No. Date of R & I & Fee	Dy. No. 11628; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	SPECLINX by Ventage Pharmaceuticals (Reg. No. 081714)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	Firm was asked to revise Spiramycin Adipate to Spiramycin Adipose and Bromhexine to Bromhexine HCL along with the submission of applicable fee. Firm in reply submitted updated form5 with correct label claim and fee of Rs.5000/ with deposit slip No. 0828983 dated 08.05.2019.
	Decision:Approved with innovator's specification.	
753.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	NEOXYCOLIN POWDER
	Composition	Each 1000 gm Contains:- Oxytetracycline HCL……250 gm Neomycin Sulphate……..250 gm Colistin Sulphate…….. …..300 M.I.U
	Diary No. Date of R & I & Fee	Dy. No. 11622; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A

	Me-too Status	OXYCOL FORTE by Attabak Pharmaceuticals (Reg.# 071068)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	
	Decision:Approved with innovator's specification.	
754.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	DOXYCOL-T POWDER
	Composition	Each 100 gm Contains :- Tylosin Tartrate……..10 gm Doxycycline HCL……..20 gm Colistin Sulphate……3 gm Bromhexine HCL……...1 gm
	Diary No. Date of R & I & Fee	Dy. No. 11641; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	BIOSIN TD by Leads Pharma (Reg. No. 044951)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	Firm mentioned different strength on label claim and Master Formula, Firm was asked to Clarify/Justify. Firm in reply submitted revised form 5 but which is not as per Me-too.
	Decision:Deferred for submission of fee for revision of formulation.	
755.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	U-DOX-25 POWDER
	Composition	Each 100 gm Contains:- Doxycycline Hyclate Eq. to Doxycycline Base……25 gm
	Diary No. Date of R & I & Fee	Dy. No. 11635; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Tetracycline
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	UNIDOX-25% by Univet Pharmaceuticals (Reg. No. 029642).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	Firm was asked to revise Doxycycline to "Doxycycline Hyclate eq.to 25gm Doxycycline Base" in label claim and Master Formula along with the submission of applicable fee. Firm in reply submitted updated Form5 with fee of Rs.5000/ with deposit slip No. 0828984 dated 08.05.2019.
	Decision: Approved with Innovator's specification.	
756.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	PARAZOL POWDER
	Composition	Each 100 gm Contains :- Paracetamol……..20 gm Vitamin C…….5 gm

		Potassium Carbonate……12.5 gm Sodium Bicarbonate…….12.5 gm Vitamin E……1.25 gm
	Diary No. Date of R & I & Fee	Dy. No. 11640; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	POZADOL by Leads Pharmaceuticals (Reg. No. 084969)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specification.	
757.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	AMANTEX-98% POWDER
	Composition	Each 100 gm Contains:- Amantadine HCL……98 gm
	Diary No. Date of R & I & Fee	Dy. No. 11653; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Anti Parkinsons
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	Emanta-98 by Evergreen Pharmaceuticals (Reg. No. 081735).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	
	Decision: Approved with Innovator's specification.	
758.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	NCO-FORTE POWDER
	Composition	Each 1000 gm Contains:- Oxytetracycline HCL……..300 gm Neomycin Sulphate…….250 gm Colistin Sulphate…….. ..500 M.I.U
	Diary No. Date of R & I & Fee	Dy. No. 11647; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	OXYNEORIQ-C by Baariq Pharmaceuticals (Reg. No. 073952).
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	Firm was asked to mention correct label claim form "Oxytetracycline" to "Oxytetracycline HCL" on form 5 with updated form5 and applicable fee. The firm in reply submitted updated form5 with correct label claim and fee of Rs.5000/ with deposit slip No. 0828985 dated 08.05.2019.
	Decision:Approved with Innovator's specification.	

759.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	ST-S3 POWDER
	Composition	Each 100 gm Contains:- Sulphachlorpyrazine Sodium as (Sulphachlozine Sodium Salt Monohydrate)….. ……30 gm
	Diary No. Date of R & I & Fee	Dy. No. 11642; 06-03-2019; Rs. 20,000/- (01-03-2019)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100gm, 500gm, 1Kg, 2.5 kg, 5 kg, 25 kg : Decontrolled
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	SB-S3 by SB Pharmaceuticals (Reg. No. 028538)
	GMP Status	New License (Inspection Date: 04-10-2018 & 05-11-2018). DML issued on 05.03.19.
	Remarks of the Evaluator	Firm was asked to correct label claim and add salt with API along with submission of applicable fee and updated Form5. Firm in reply submitted revised form5 with correct label claim and fee of Rs.5000/ with deposit slip No.0828986 Dated 08.05.2019.
	Decision: Approved with Innovator's specification.	

Evaluator PEC-IV

Case no. 01: Registration Applications for Local Manufacturing of (Human) Drugs.

a. New Cases.

760.	Name and address of manufacturer / Applicant	Hamaz Pharmaceuticals (pvt) Ltd, 13 KM Bosan Road, Multan
	Brand Name +Dosage Form + Strength	Nefox Tablet 100mg
	Composition	Each tablet contains:- Nimesulide……..100mg
	Diary No. Date of R& I & fee	Dy.No 348 dated 03.03.2015 Rs.8000/- 06-07-10 Rs.12000/= 02.03.2015
	Pharmacological Group	NSAID Cox-2 Inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	20's; Rs. 100/
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (with strength and dosage form)	Nimside Tablets 100mg.of M/s Novamed Pharmaceuticals
	GMP status	Last GMP inspection conducted on 17-01-2018., and the report concludes that the firm was considered to be operating at satisfactory level of compliance to the cGMP
	Remarks of the Evaluator[4]	
	Decision: Keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board approved the applied formulation of Nimesulide Tablets 100mg with innovator's specifications and a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. • **Treatment of acute pain** • **Primary dysmenorrhea**	
761.	Name and address of manufacturer / Applicant	Hamaz Pharmaceuticals (pvt) Ltd, 13 KM Bosan Road, Multan
	Brand Name +Dosage Form + Strength	Rockcef Suspension 250mg

	Composition	Each 5ml contains:- Cephradine USP….250mg
	Diary No. Date of R& I & fee	Dy.No 356 dated 03.03.2015. Rs.8000/- 05-07-10 Rs.12000/= 02.03.2015
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP Specs
	Pack size & Demanded Price	60ml bottle; Rs 128/pack
	Approval status of product in Reference Regulatory Authorities	Velocef of USFDA discontinued
	Me-too status (with strength and dosage form)	Cephrascot suspension by M/s Scotmann Pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator[4]	
	Decision: Approved as suspension based upon approval status in USFDA and available metoo.	
762.	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	Tamsin-0.4mg SR Capsule
	Composition	Each Capsule Contains: Tamsulosin HCL SR pellets 0.2% w/w eq. to Tamsulosin HCL……0.4mg
	Diary No. Date of R& I & fee	Dy.No;25214 19-12-2017 Rs. 20,000-(18-12-2017)
	Pharmacological Group	Alpha blocker
	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	Contiflo xl capsule of (MHRA approved)
	Me-too status (with strength and dosage form)	Alfamax tablet M/s Platinum Pharmaceuticals,
	GMP status	The last GMP inspection conducted on 01-03-2018 & report concludes that current level of compliance was noted as satisfactory.
	Remarks of the Evaluator[4]	• Source of pellets : Vision Pharmaceuticals
	Decision: Approved with innovator's specification.	
763.	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	Eslor 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy.No 5312 dated 14-02-2018 Rs. 20,000/- 13-02-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's ; As per PRC
	Approval status of product in Reference Regulatory Authorities	CLARINEX of USFDA approved
	Me-too status	Larinex Tablets of M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 20-03-2018., and the report concludes that the firm was considered to be operating at an acceptable level of compliance to the cGMP
	Remarks of the Evaluator[4]	
	Decision: Approved	
764.	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	Alpha Keto Tablets

	Composition	Each film coated tablet contains: Alpha-Keto phenyl alanine,Ca Salt…….68mg Alpha-Hydroxymethionine,Ca Salt……59mg Alpha-Keto isoleucine,Ca Salt…..…67mg Alpha-Keto leucine,Ca Salt……..101mg Alpha-Keto valine,Ca Salt……86mg L-Tryptophan……23mg L-Threonine…….53mg L-Tyrosine……30mg L-Histidine……...38mg L-Lysine.....105mg
	Diary No. Date of R& I & fee	Dy.No 5313 dated 14-02-2018 Rs. 20,000/- 13-02-2018
	Pharmacological Group	Amino-Acids
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	50's, 100's ; As per PRC
	Approval status of product in Reference Regulatory Authorities	KETOSTERIL by Fresenius Kabi, Germany.(Bfarm approved)
	Me-too status (with strength and dosage form)	Ketoalfa Tablets M/s Genome Pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specification.	
765.	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	Fibrogel-M Sachet
	Composition	Each Sachet contains: Ispaghula husk…3.5gm Mebeverine HCl…135mg
	Diary No. Date of R& I & fee	Dy.No 5308 dated 14-02-2018 Rs. 20,000/- 13-02-2018
	Pharmacological Group	Anti-Spasmodic
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's, 30's ; As per PRC
	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 (with strength and dosage form)	Colospas Fibro 135mg/3.5g powder by M/s Nabiqasim. (Reg#058672)
	GMP status	As recorded for above application
	Remarks of the Evaluator[4]	•
	Decision: Approved with innovator's specification.	
766.	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	Panzet 40mg Tablet
	Composition	Each Gastro Resistant Tablet contains: Pantoprazole (as Sodium Sesquihydrate)…40mg
	Diary No. Date of R& I & fee	Dy.No 5314 dated 14-02-2018 Rs. 20,000/- 13-02-2018
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 14's, , ; As per PRC
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40 mg Tablet Of (MHRA Approved)
	Me-too status (with strength and dosage form)	Pantopraz 40mg Tablet M/s Klifton Pharma,
	GMP status	As recorded for above application

	Remarks of the Evaluator[4]	
	Decision: Approved	
767.	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	Snapta 50mg Tablet
	Composition	Each film coated tablet contains: Sertraline (as HCl)…50mg
	Diary No. Date of R& I & fee	Dy.No 5311 dated 14-02-2018 Rs. 20,000/- 13-02-2018
	Pharmacological Group	Anti depressant
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, 30's ; As per PRC
	Approval status of product in Reference Regulatory Authorities	Zoloft Tablet Of (USFDA Approved)
	Me-too status (with strength and dosage form)	Ertalin 50 mg Tablets M/s Genome Pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator[4]	
	Decision: Approved	
768.	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	Lastine 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy.No 5309 dated 14-02-2018 Rs. 20,000/- 14-02-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	10's, 20's ; As per PRC
	Approval status of product in Reference Regulatory Authorities	EBASTINE ARROW 10 mg film-coated tablets ANSM Approved
	Me-too status (with strength and dosage form)	Atmos Tablets 10mg of M/s Scotmann Pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator[4]	•
	Decision: Approved with change of brand name.	
769.	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	Noatrin-D 20mg Tablet
	Composition	Each Dipersible tablet contains: Piroxicam (as Betacyclodextrin)…20mg
	Diary No. Date of R& I & fee	Dy.No 5310 dated 14-02-2018 Rs. 20,000/- 13-02-2018
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength and dosage form)	Infladex Dispersible Tablets of M/s Gray's Pharmaceuticals
	GMP status	As recorded for above application
	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. • (Only piroxicam in reference product)

	Decision: 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.	
770.	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	Claron 125mg/5ml Suspension
	Composition	Each 5ml Contains: Clarithromycin as taste masked granules 38%…125mg
	Diary No. Date of R& I & fee	Dy.No;25246 19-12-2017 Rs. 20,000-(19-12-2017)
	Pharmacological Group	Antibiotic (Macrolide)
	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 29-11-2018 and the report concludes that firm was considered to be operating at Satisfactory level of compliance with GMPguidelines
	Remarks of the Evaluator[4]	• Source of pellets; Surge Laboratories • (22-02-2018 GMP certificate)
	Decision: Approved	
771.	Name and address of manufacturer / Applicant	M/S Welwrd Pharmaceuticals, Plot No ; 3, Block A, Phase I – II, Industrial Estat,Hattar, Pakistan Contract manufactured by M/S Wnsfeild Pharmaceuticals, Hattar Pakistan.
	Brand Name +Dosage Form + Strength	Welgest 10mg tablet
	Composition	Each film tablet contains: Dydrogesterone……10mg
	Diary No. Date of R& I & fee	Dy.No.10556; 31-07-2017; Rs.50,000/- (31-07-2017)
	Pharmacological Group	Progesterone
	Type of Form	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 (Swissmedic Approved)
	Me-too status (with strength and dosage form)	Duphaston by Abbott (Reg. No. 006654)
	GMP status	Last GMP inspection of Welwrd conducted on 12-11-2018 and the report concludes that firm is operating at satisfactory level GMP & Last GMP inspection of Wnsfeild conducted on 18-01-2018 and the report concludes renewal of DML
	Remarks of the Evaluator	• Contract manufacturing agreement: Attached • Number of sections of applicant approved by Licensing Board:08 • Number of products already registered/approved on contract manufacturing in the name of applicant: 02
	Decision: Approved	

B. DEFERRED CASES:

772.	Name and address of manufacturer / Applicant	M/s Dr Raza Pharma, B-4, Plot No. 44- C, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Lipidase 10mg Tablets
	Composition	Each tablet contains:- Atorvastatin (as calcium trihydrate salt)……10mg
	Diary No. Date of R& I & fee	Dy.No :Duplicte 8-3-2011 Rs.8000/- Rs.12000/- Dated 14-1-2015
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	10's; 20's; 30's As Per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status (with strength and dosage form)	Lipitor of M/s Pfizer
	GMP status	Last inspection conducted on 06-08-2018 and report concludes that overall the cGMP compliance is saisfactory.
	Previous remarks of the Evaluator.	
	Previous decision(s)	**Deferred for following reasons:** 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**. (M-285)**
	Evaluation by PEC	Last inspection conducted on 24-01-2019 and report concludes that overall the cGMP compliance is satisfactory.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board.	
773.	Name and address of manufacturer / Applicant	M/s Dr Raza Pharma, B-4, Plot No. 44- C, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	DS-100 SR Capsules
	Composition	Each capsule contains:- Diclofenac Sodium Pellets equivalent to Diclofenac....100mg
	Diary No. Date of R& I & fee	Dy.No :Duplicte 8-3-2011 Rs.8000/- Rs.12000/- Dated 14-1-2015
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP Specs
	Pack size & Demanded Price	10's; 20's; 30's As Per SRO
	Approval status of product in Reference Regulatory Authorities	Diclofenac Sodium of USFDA approved
	Me-too status (with strength and dosage form)	Dicast S.R Tablets of M/s Winbrain Research Laboratories
	GMP status	As recorded for above application
	Previous remarks of the Evaluator.	Source of pellets: Vision pharma
	Previous decision(s)	**Deferred for following reasons:** 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**.(M-285)**
	Evaluation by PEC	Last inspection conducted on 24-01-2019 and report concludes that overall the cGMP compliance is satisfactory.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board.	
774.	Name and address of manufacturer / Applicant	M/s Dr Raza Pharma, B-4, Plot No. 44- C, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Trizol Suspension

	Composition	Each 5ml contains:- Sulphamethoxazole…..200mg Trimethoprim…….40mg
	Diary No. Date of R& I & fee	Dy.No :Duplicte 8-3-2011 Rs.8000/- Rs.12000/- Dated 14-1-2015
	Pharmacological Group	Sulphonamide
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	50ml; As Per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Trimoxazole of MHRA approved
	Me-too status (with strength and dosage form)	Cotazole Suspension of M/s Meditech Pharmaceuticals
	GMP status	As recorded for above application
	Previous remarks of the Evaluator.	
	Previous decision(s)	**Deferred for following reasons:** 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.**(M-285)**
	Evaluation by PEC	Last inspection conducted on 24-01-2019 and report concludes that overall the cGMP compliance is satisfactory.
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board.	
775.	Name and address of manufacturer / Applicant	CSH Pharamaceuticals (Pvt) Ltd., 32-Km, Ferozepur road, Lahore
	Brand Name +Dosage Form + Strength	Clavicin 375mg Dispersible Tablets
	Composition	Each dispersible tablet contains:- Amoxicillin Trihydrate……250mg Clavulanic Acid…..125mg
	Diary No. Date of R& I & fee	Dy.No : 590 (Duplicate) 25-02-2013
	Pharmacological Group	Beta – lactamase inhibitor, Broad spectrum penicillin
	Type of Form	Form 5
	Finished product Specifications	Manufacturer spec
	Pack size & Demanded Price	1x6's; Rs :300/ 1x 6's
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength and dosage form)	Amclav 375mg Tablet of M/s Getz
	GMP status	Last GMP inspection was conducted on 27-09-2017 and report concludes that panel recommend the renewal of DML
	Previous 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.
	Previous decision(s)	**Deferred for following reasons:** 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	Augmentin dispersible tablets 250mg/125mg by EMA approved
	Decision: Approved with innovator's specification. Fee shall be verified as per procedure adopted by Registration Board.	
776.	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	Claricure SR 500mg Tablet
	Composition	Each film coated tablet contains: Clarithromycine…….500 mg
	Diary No. Date of R& I & fee	Dy.No.9792`; 24-07-2017; Rs.20,000/- (14-07-2017)

	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	Klaricid of (MHRA approved)
	Me-too status	Respect tablet M/s Spencer Pharmaceutical
	GMP status	Last GMP inspection is conducted on 24- 04- 2018 and the report concludes that overall firm has satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	**Deferred for following reasons:** Registration Board directed the firm to submit clarification regarding applied dosage form whether sustained release or otherwise **(M-283)**
	Evaluation by PEC	Firm reply that Claricure SR 500mg is sustained release product
	Decision: Approved.	
777.	Name and address of manufacturer / Applicant	Prays Pharmaceuticals, Plot # , Street SS, National Industrial Zone (RCCI) Rawat, Islamabad **Manufactured by:** Bio Labs (Pvt) Ltd, Plot#, Industrial Triangle, Kahuta Road Islamabad
	Brand Name+Dosage Form + Strength	Sun-D Injection
	Composition	Each ml contain: Cholecalciferol.....5mg (eq. To 200,000 IU)
	Diary No. Date of R& I & fee	Dy.No:707 ; 02-02-2015; Rs.250,000/-
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished product Specifications	(BP Spec's)
	Pack size & Demanded Price	5ml x 10's As per PRC
	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	
	Previous remarks of the Evaluator.	• 1st Letter: 09th March , 2018 • Reminder Letter: 24th April , 2018 • Latest GMP inspection report (which should have been conducted within the period of last one year). • Contract agreement. • No. of already registered contract manufactured products. • Revise Form -5 by applicant (Prays pharma)
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for further deliberation **(M-284)**
	Evaluation by PEC	•No. of already registered contract manufactured products: No •Revise Form -5 by applicant (Prays pharma): Submitted
	Decision: Approved with change of brand name	
778.	Name and address of manufacturer / Applicant	Prays Pharmaceuticals, Plot # , Street SS, National Industrial Zone (RCCI) Rawat, Islamabad **Manufactured by:** (Previous) Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad. (Now) Nicholas Pharmaceuticals, Plot # 34 St # SS-02 National Industrial Zone Rawat Islamabad Pakistan.
	Brand Name+Dosage Form + Strength	Prayxone Injection 250mg IV
	Composition	Each vial contain: Ceftriaxone Sodium Eq. To Ceftriaxone.....250mg

	Diary No. Date of R& I & fee	Dy. No. 709; 02-02-2015 ; Rs. 50,000/-
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too status (with strength and dosage form)	Wincef 250 mg IV Injection M/s Wel Wink Pharmaceuticals,
	GMP status	
	Previous remarks of the Evaluator.	• Letter: 24th April , 2018 • Latest GMP inspection report (which should have been conducted within the period of last one year). • Original contract agreement. • No. of already registred contract manufactured products • Revise Form -5 by applicant (Prays pharma). • Seprate dossier should be submitted for Ceftriaxon I.V and I.M as separate registeration is granted to these 2 routes. So clarification is required for which routes of administration you want to apply this dossier along wih its diluent.
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for further deliberation **(M-284)**
	Evaluation by PEC	• No. of already registered contract manufactured products: No • Revise Form -5 by applicant (Prays pharma): Submitted • Firm change manufacturing facility from Biolabs to Nicholas Pharmaceuticals • Applied for IV route • Last inspection of Nicholas Pharmaceuticals is conducted on 03- 08- 2018 and the report concludes that "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule(Cephalosporin) 2- Dry suspension section(Cephalosporin) 3- Dry powder Injectable section(Cephalosporin) 4- Dry powder Injectable section(Carbapenems)"
	Decision: Approved	
779.	Name and address of manufacturer / Applicant	Prays Pharmaceuticals, Plot # , Street SS, National Industrial Zone (RCCI) Rawat, Islamabad **Manufactured by:** (Previous) Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad. (Now) Nicholas Pharmaceuticals, Plot # 34 St # SS-02 National Industrial Zone Rawat Islamabad Pakistan.
	Brand Name +Dosage Form + Strength	Prayxone Injection 500mg IV
	Composition	Each vial contain: Ceftriaxone Sodium Eq. To Ceftriaxone.....500mg
	Diary No. Date of R& I & fee	Dy. No. 708; 02-02-2015; Rs. 50,000/-
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)

	Me-too status (with strength and dosage form)	Wincef 500 mg IV Injection M/s Wel Wink Pharmaceuticals,
	GMP status	
	Previous remarks of the Evaluator.	• Letter: 24th April , 2018 • Latest GMP inspection report (which should have been conducted within the period of last one year). • Original contract agreement. • No. of already registred contract manufactured products • Revise Form -5 by applicant (Prays pharma). • Seprate dossier should be submitted for Ceftriaxon I.V and I.M as separate registeration is granted to these 2 routes. So clarification is required for which routes of administration you want to apply this dossier along wih its diluent.
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for further deliberation **(M-284)**
	Evaluation by PEC	• No. of already registered contract manufactured products: No • Revise Form -5 by applicant (Prays pharma): Submitted • Firm change manufacturing facility from Biolabs to Nicholas Pharmaceuticals • Applied for IV route • Last inspection of Nicholas Pharmaceuticals is conducted on 03- 08- 2018 and the report concludes that **"**Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule(Cephalosporin) 2- Dry suspension section(Cephalosporin) 3- Dry powder Injectable section(Cephalosporin) 4- Dry powder Injectable section(Carbapenems)"
	Decision: Approved	
780.	Name and address of manufacturer / Applicant	Prays Pharmaceuticals, Plot # , Street SS, National Industrial Zone (RCCI) Rawat, Islamabad **Manufactured by:** (Previous) Bio Labs (Pvt) Ltd, Plot #, Industrial Triangle, Kahuta Road Islamabad. (Now) Nicholas Pharmaceuticals, Plot # 34 St # SS-02 National Industrial Zone Rawat Islamabad Pakistan.
	Brand Name +Dosage Form + Strength	Prayxone Injection 1gm IV
	Composition	Each vial contain: Ceftriaxone Sodium Eq. To Ceftriaxone.....1gm
	Diary No. Date of R& I & fee	Dy. No. 710; 02-02-2015 ; Rs. 50,000/-
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin I.V injection of (MHRA approved)
	Me-too status (with strength and dosage form)	Trivolive 1gm Injection I.V M/s Olive Pharmaceuticals
	GMP status	
	Previous remarks of the Evaluator.	• Letter: 24th April , 2018 • Latest GMP inspection report (which should have been conducted within the period of last one year).

		• Original contract agreement. • No. of already registred contract manufactured products • Revise Form -5 by applicant (Prays pharma). • Seprate dossier should be submitted for Ceftriaxon I.V and I.M as separate registeration is granted to these 2 routes. So clarification is required for which routes of administration you want to apply this dossier along wih its diluent.
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for further deliberation **(M-284)**
	Evaluation by PEC	• No. of already registered contract manufactured products: No • Revise Form -5 by applicant (Prays pharma): Submitted • Firm change manufacturing facility from Biolabs to Nicholas Pharmaceuticals • Applied for IV route • Last inspection of Nicholas Pharmaceuticals is conducted on 03- 08- 2018 and the report concludes that **"**Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously recommend the M/s Nicholas for the grant of DML and sections: 1- Capsule(Cephalosporin) 2- Dry suspension section(Cephalosporin) 3- Dry powder Injectable section(Cephalosporin) 4- Dry powder Injectable section(Carbapenems)"
	Decision: Approved	
781.	Name and address of manufacturer / Applicant	M/S Welmark Pharmaceuticals, Plot No ; 122, Block B, Phase-V, Industrial Estat,Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Weltop 25mg Tablet
	Composition	Each film coated tablet contains: Topiramate…….25mg
	Diary No. Date of R& I & fee	Dy.No.20413; 08-11-2017; Rs.20,000/- (24-10-2017)
	Pharmacological Group	Antiepileptic agent
	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 Of (USFDA Approved)
	Me-too status (with strength and dosage form)	Lowseiz 25mg Tablets of M/S Helix Pharma
	GMP status	Last GMP inspection was conducted on 16-09-2017 and the report concludes that overall firm was GMP compliant
	Previous remarks of the Evaluator.	Letter No.F.33-1/2018-REG-IV(2nd PRVC) dated:6th April,2018 from REG-IV that following application recived for export registeration and later firm informed that application is for local registration.
	Previous decision(s)	**Deferred for following reasons:** Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm**.(M-285)**
	Evaluation by PEC	Last inspection conducted on 04-09-2018 & 26-09-2018. and report concludes that **"**As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the

		renewal of DML 000614 by way of formulation granted to M/s Welmark KPK**".**
	Decision: Approved	
782.	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	Leucoarte CA 30mg/10ml Solution for Injection
	Composition	Each 10ml of ampule Contains: Folinic Acid as Calcium Folinate……30mg
	Diary No. Date of R& I & fee	Dy.No;25450 21-12-2017 Rs. 20,000-(21-12-2017)
	Pharmacological Group	Detoxifying agent for antineoplastic treatment
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	1's, 10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	REFOLINON 3MG/ML SOLUTION FOR INJECTION Of MHRA Approved
	Me-too status (with strength and dosage form)	Not found
	GMP status	Date of latest Inspection: 16-02-2018 M/s Genix Pharma Pvt. Ltd Karachi was considered at an satisfactory level of compliance with CGMP GUIDLINES as of today. The management was also suggested to further strengthen stability and analytical sections."
	Previous remarks of the Evaluator.	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm
	Previous decision(s)	**Deferred for following reasons:** 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-287)**
	Evaluation by PEC	Due to typographical error the strength was written 30mg/10ml instead of 30mg/3ml (10mg/ml) corrected formulation is **LeucoArt CA 30mg/3ml Solution for injection** **Each 3ml of Ampoule contains:** **Folinic Acid as calcium folinate……30mg (10mg/ml)** • Calcium Folinate 10mg/ml (Fill volume 3ml) Austria approved • Kunyrin Injection 30mg/3ml Of M/S Al-Habib Pharmaceuticals • Fee for correction RS: 20000/- Deposited through challan No: 0829498 dated : 20-03-2019
	Decision: Approved with innovator's specification.	
783.	Name and address of manufacturer / Applicant	M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan Contract manufactured by: Previous: M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad. 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: 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 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." & 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 • Number of products already registered/approved on contract manufacturing in the name of applicant: 12
	Previous decision(s) **(M-285)**	Deferred for following reasons: 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.
	Previous decision(s) **(M-288)**	Deferred for following reasons Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm **(M-288)**
	Evaluation by PEC	Last inspection of Winthrox conducted on 09-10-2018 and report concludes that overall GMP compliance is rated as good.
	Decision: Approved	
784.	Name and address of manufacturer / Applicant	M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan Contract manufactured by: Previous: M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad. 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: Cholecalciferol (Vitamin D3) …….5mg (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 " 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." & 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 • Number of products already registered/approved on contract manufacturing in the name of applicant: 12
	Previous decision(s) **(M-285)**	Deferred for following reasons: 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.
	Previous decision(s) **(M-288)**	Deferred for following reasons Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm **(M-288)**
	Evaluation by PEC	Last inspection of Winthrox conducted on 09-10-2018 and report concludes that overall GMP compliance is rated as good.
	Decision: Approved	
785.	Name and address of manufacturer / Applicant	M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan Contract manufactured by: Previous: M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad. 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: 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 " 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." & 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 • Number of products already registered/approved on contract manufacturing in the name of applicant: 12
	Previous decision(s) **(M-285)**	Deferred for following reasons: 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.
	Previous decision(s) **(M-288)**	Deferred for following reasons Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm **(M-288)**
	Evaluation by PEC	Last inspection of Winthrox conducted on 09-10-2018 and report concludes that overall GMP compliance is rated as good.
	Decision: Approved with innovator's specification.	
786.	Name and address of manufacturer / Applicant	M/S Welmed Pharmaceuticals Industries (Pvt) Ltd., 108, R:2 Industrial Estat,Gadoon, District Swabi, Pakistan Contract manufactured by: Previous: M/S Biolabs (Pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road Islamabad. 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: 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 " 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."

		& 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 • Number of products already registered/approved on contract manufacturing in the name of applicant: 12
	Previous decision(s) **(M-285)**	Deferred for following reasons: 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.
	Previous decision(s) **(M-288)**	Deferred for following reasons Deferred for updated status of GMP of the firm "Winthrox" form QA & LT division as inspection report was not submitted by firm **(M-288)**
	Evaluation by PEC	Last inspection of Winthrox conducted on 09-10-2018 and report concludes that overall GMP compliance is rated as good.
	Decision: Approved	
787.	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: 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
	Previous remarks of the Evaluator.	Correction of Salt form Rosuvastatin as calcium without submission of fee
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of formulation**.(M-287)**
	Evaluation by PEC	Rs:5000/= fee submitted through challan No;0841674 dated: 14-02-2019
	Decision: Approved with innovator's specification.	
788.	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: 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	As recorded for above application
	Previous remarks of the Evaluator.	Correction of Salt form Rosuvastatin as calcium without submission of fee
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of formulation**. (M-287)**
	Evaluation by PEC	Rs:5000/= fee submitted through challan No;0841675 dated: 14-02-2019
	Decision: Approved with innovator's specification.	
789.	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: 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	As recorded for above application
	Previous remarks of the Evaluator.	Correction of Salt form Rosuvastatin as calcium without submission of fee
	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of formulation**. (M-287)**
	Evaluation by PEC	Rs:5000/= fee submitted through challan No;0841676 dated: 14-02-2019
	Decision: Approved with innovator's specification.	
790.	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: 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 (R# 039302)
	GMP status	As recorded for above application
	Previous remarks of the Evaluator.	Correction of Salt form Eperisone as HCl without submission of fee .

	Previous decision(s)	**Deferred for following reasons:** Deferred for submission of fee for revision of formulation**.** **(M-287)**
	Evaluation by PEC	Rs:5000/= fee submitted through challan No;0841677 dated: 14-02-2019
	Decision: Approved with innovator's specification.	

Case No. 02: 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)	05	10
Dry powder injection (Cephalosporin)		
Dry powder suspension (Cephalosporin)		

The letter was issued on 8th January 2019.

Capsule (Cephalosporin) 10 Products/ 05 Molecules		
791.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Ceficlor 250mg Capsule
	Composition	Each Capsule Contains: Cefaclor Monohydrate Eq. to Cefaclor…250mg
	Diary No. Date of R& I & fee	Dy.No 3384 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefaclor Capsules 250mg (Cefaclor monohydrate Ph Eur Eq. to 250mg of Cefaclor) by Strides Pharma UK Ltd. Approved by MHRA
	Me-too status (with strength and dosage form)	Resclor 250 mg Capsules by M/s Genome Pharmaceuticals
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	
792.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Ceficlor 500mg Capsule
	Composition	Each Capsule Contains: Cefaclor Monohydrate Eq. to Cefaclor…500mg
	Diary No. Date of R& I & fee	Dy.No 3385 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefaclor Capsules 500mg (Cefaclor monohydrate Ph Eur Eq. to 500mg of Cefaclor) by Strides Pharma UK Ltd. Approved by MHRA
	Me-too status (with strength and dosage form)	Resclor 500 mg Capsules by M/s Genome Pharmaceuticals

	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	
793.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Rulex 250mg Capsule
	Composition	Each Capsule Contains: Cephalexin Monohydrate Eq to Cephalexin…250mg
	Diary No. Date of R& I & fee	Dy.No 3386 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cephalexin Capsules of USFDA approved
	Me-too status (with strength and dosage form)	Defmat 250mg Capsule by M/s Martin Dow
	GMP status	New license
	Remarks of the Evaluator	
	Decision:	
794.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Rulex 500mg Capsule
	Composition	Each Capsule Contains: Cephalexin Monohydrate Eq to Cephalexin…500mg
	Diary No. Date of R& I & fee	Dy.No 3388 dated 24-01-2019 Rs.20,000/- Dated 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cephalexin Capsules of USFDA approved
	Me-too status (with strength and dosage form)	Defmat 500mg Capsule by M/s Martin Dow
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	
795.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Cecil 500mg Capsule
	Composition	Each Capsule Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…500mg
	Diary No. Date of R& I & fee	Dy.No 3390 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefadroxil Capsules of MHRA approved
	Me-too status (with strength and dosage form)	Gabadrox 500mg Capsule by M/s Gaba Pharma
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	

796.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Cecil 1g Capsule
	Composition	Each Capsule Contains: Cefadroxil Monohydrate Eq. to Cefadroxil…1000mg
	Diary No. Date of R& I & fee	Dy.No 3391 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not found
	Me-too status	Gabadrox 1g Capsule by M/s Gaba Pharma
	GMP status	New license
	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.
	Decision: 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.	
797.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Cefrid 250mg Capsule
	Composition	Each Capsule Contains: Cephradine Monohydrate Eq. to Cephradine…250mg
	Diary No. Date of R& I & fee	Dy.No 3388 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefradine Capsules of MHRA approved
	Me-too status	Zasinol 250mg capsule byM/s Martin Dow (Reg#080643)
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	
798.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Cefrid 500mg Capsule
	Composition	Each Capsule Contains: Cephradine Monohydrate Eq. to Cephradine…500mg
	Diary No. Date of R& I & fee	Dy.No 3386 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cefradine Capsules of MHRA approved
	Me-too status	Dinar 500mg capsule by Baxter Pharma
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	
799.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Micef 200mg Capsule
	Composition	Each Capsule Contains: Cefixime Trihydrate Eq. to Cefixime…200mg

	Diary No. Date of R& I & fee	Dy.No 3382 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	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	CEFIXIMA NORMON 200 mg CAPSULAS by M/s Laboratorios Normon, S.A., Spain approved
	Me-too status (with strength and dosage form)	Xime 200 mg Capsulesby M/s Fedro Pharmaceutical,
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	
800.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Micef 400mg Capsule
	Composition	Each Capsule Contains: Cefixime Trihydrate Eq. to Cefixime…400mg
	Diary No. Date of R& I & fee	Dy.No 3383 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	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	Suprax of (USFDA approved)
	Me-too status (with strength and dosage form)	Maxophine Capsules of M/s Global Pharmaceuticals,
	GMP status	New license
	Remarks of the Evaluator	
	Decision: Approved	

Case No. 03: Registration Applications of Import Cases.

a. New Cases (Human)

801.	Name and address of Applicant	M/s Muller & Phipps Pakstan (Pvt) Ltd., Uzma court, Main Clifton Road, P.o Box 3880 karachi- 75600 Pakistan
	Detail of Drug Sale License	Address:Plot No. 208& 208/1 sector 23 Korangi Industrial Area Karachi. Validity : 03/10/2019 Status: drug to sell drugs in a wholesale distributor
	Name and address of manufacturer	M/s Fresenius Kabi Austria GmbH Hafnerstrasse 36 A-8055 Graz / Austria
	Name and address of marketing authorization holder	M/s Fresenius Kabi Deutschland GmbH D- 61346 Bad Homburg v. d. Hohe
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 1548 Dated : 04/05/2017
	Fee including differential fee	Rs : 1,00,000 Dated : 04/05/2017
	Brand Name +Dosage Form + Strength	SMOFlipid 20% emulsion for Infusion
	Composition	1000ml contains : Soya-bean oil,refined…….....60gm Triglycerides,medium chain……....60gm Oliv oil, refined……...50gm Fishg oil, rich in omega 3- acids…….30gm
	Finished Product Specification	Inhouse Specifications
	Pharmacological Group	Fat Emulsion (Solution for parenteral nutrition)

	Shelf life	24 months	
	Demanded Price	10 x 100ml Rs; 6470.5/- Unite Price of one bottle Rs; 647.5/- 10 x 250ml Rs; 10059/- Unite price of one bottle Rs; 1005.90/- 10 x 500ml Rs; 19706/- Unite price of one bottle Rs; 1970.60/-	
	Pack size	250ml,	
	International availability	USFDA Approved	
	Me-too status	N/A	
	Detail of certificates attached	Valid and Legalized CoPP Certificate No: ROBQ4 Certified by: Regierungsprasiddiun Darmstadt Luisenplatz 2 d-64278 Darmstadt Issued on : 07/02/2017 Free sale: Confirms the free sale of the product in exporting country. GMP certificate GMP certificate No : INS-480166-0085-001(13/15) Date of Inspection: 05-02-2018 Valid until : 3 years Sole Contract Agreement 16-04-2018	
	Remarks of the Evaluator.	Short coming communicated	Reply of firm
		Address on form 5-A and address on Drug sale License is change	This is to certify that Muller & Phipps Pakistan (Pvt) Ltd, has registred office at Uzma court, Main Clifton Road, P.o Box 3880 karachi- 75600 Pakistan and our central warehouse is located at plot No 208 & 208/1, Sector -23, Korangi Industrial area Karachi, Where the products are recived, stored and transferred to other M&P establishment all over the Pakistan.
		Stability study data for real time is not for 3 batches.	2 batches (WA1519 and WA1523) were put on stability at 30°C in order to gather more information about the product As this temperature was used for stability solely as a back-up (at that time), not all batches were put on stability at 30°C
		Accelerated stability study is performed at 40°C ± 2°C / NMT 25%RH in glass container . Please clarify.	Accelerated studies were performed with the original primary packaging material, which is glass container = see ICH Topic Q 1 A (R2) 2.2.4 Container-closure system: "Stability testing should be conducted on the dosage form packaged in the primary container-closure

			systems proposed for marketing(including , as appropriate, any secondary packaging and container label). Any available studies carried out on the FPP outside its immediate container or in other packaging materials can form a useful part of the stress testing of the dosage form or can be considered as supporting information, respectively. ” As glass container are impermeable containers, the relative humidity is not relevant according to ICH Topic Q 1 A (R2) 2.2.7.2 FPPs packaged in impermeable containers: “Sensitivity to moisture or potential for solvent loss is not a concern for FPPs packaged in impermeable containers that provide a permanent barrier to passage of moisture or solvent. Thus stability studies for products stored in impermeable containers can be conducted under any controlled or ambient RH condition.”
		In case of long term stability the result at 30°C of non esterified fatty acid at 24 month is out of specification. So clarify .	The registred and relevant labelled conditions for SMOFlipid 20% is up to 25°C. As it is known that SMOFlipid 20% is not stable for 24 month at 30°C , Fresenius Kabi has reduced the shelflife to 18 months in countries with a labelled storage condition of up to 30°C In future allongoing stabilities for SMOFlipid 20% at 30°C will be only tested and reported up to 18 months.
	Decision: Registration board Deferred the case for following reason: • **Submission of stability data of 3rd batch as provided data is of only 2 batches.** • **Accelerated stability study conducted at at 40°C ± 2°C /75±5%RH as per zone-IV A requirement.**		

Case No. 04: Registration Applications of Drugs for which Stability Study Data is Submitted.

a. New Cases.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
802	M/s Pharmedic Laboratories (Pvt) Ltd, 16-KM Multan Road, Lahore- Pakistan	Hepvir 400mg Tablets Each film coated tablet contains: Sofosbuvir …….400 mg Antihepatitis (Manufacturers specifications)	Form-5 29-05-2015 Dy.No.316 Rs.20,000/- 28's Rs; 55000/28	Sovaldi Tablets by US FDA approved Last inspection report 07-08-2018, 04-09-2018 & 22-11-2018 and conclusion of report is Based on the findings of the inspection and the improvements made by the firm, the panel of inspectors recommends resumption of production in the liquid injectable section (gen). 2- The matter of unauthorized production in Liquid injectable section (gen) had already been forward to the directorate of QA and LT vide letter no 11210/2018-DRAP (L-VII) dated 24-08-2018 for necessary action. 3- Firm was advised to rectify the observations made during the CGMP inspection and submit compliance report.	

STABILITY STUDY DATA	
Drug	Hepvir 400mg Tablet
Name of Manufacturer	M/s Pharmedic Laboratories (Pvt) Limited
Manufacturer of API	M/s Pharmagen Ltd., Kot nabi Bukhsh Wala, 34-KM, Ferozepur Road, Lahore
API Lot No.	00511211/001/2017
Description of Pack (Container closure system)	Alu/Alu
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH
Time Period	Accelerated: 06 Months Real Time: 06 Months

Frequency	Accelerated: 0,1,2,4,3,6 (Month) Real Time: 0,3,6(Month)		
Batch No.	SOF-TR-07	SOF-TR-08	SOF-TR-09
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	May – 2018	May – 2018	May – 2018
Date of Initiation	08-05-2017	08-05-2017	08-05-2017
No. of Batches	3		
Date of Submission	25-2-2019 (Dy. No. 8194)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA M/s Pharmagen Ltd Pakistan 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 Ref. No. 06/2019- DRAP (AD/607409-530) Dated: 11-01-2019 issued by DRAP 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.	Local source (not valid)
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

Initially submitted incomplete data of one batch that is SOF-TF-06 containing methylene chloride as excipient. Now they submitted three new trial batches with revise formulation without methylene chloride .

Decision: Registration Board deferred for updated report on GMP compliance. Incase of satisfactory report, panel shall be constituted for onsite verification of stability study.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
803	M/S Barrett Hodgson Pakistan (Pvt) Ltd. f/423, SITE, Karachi-75700- Pakistan	Eye Aid Ophthalmic Solution 0.07% Each ml contains: Bromfenac Sodium Sesquihydrate 0.0805% (eq. to Bromfenac free acid……. 0.7mg	Form 5D **New Section** 03-04-2014 Dy. No.379 Rs.50,000/- (Duplicate Dossier) 1.6ml/ Rs: 575/-	Prolensa 0.07% ophthalmic solution US FDA Last inspection report 20-02-2018 and report concludes that firm is operating at satisfactory level of GMP compliance.	

		Non-Steroidal anti-inflammatory (Manufacturers specifications)	3ml/RS:1025/- 5ml/Rs:1695/-		

STABILITY STUDY DATA			
Drug	Eye Aid Ophthalmic Solution 0.07%		
Name of Manufacturer	M/S Barrett Hodgson Pakistan (Pvt) Ltd.		
Manufacturer of API	M/s Enaltec Labs 17th floor, Kesar Solitaire Plot No: 5, Sector19, Sanpada Navi Mumbai, Maharashtra		
	M/s Indoco remedies limited, Kilo Lab R-92 – 93, T.T.C, MIDC, Thane Belapur Road, Rabble, New Mumbai		
API Lot No.	M/s Enaltec Labs	EL- 03/A007/13002	
	M/s Indoco remedies	RK13BRN001	
Description of Pack (Container closure system)	LDPE		
Stability Storage Condition	Accelerated: 40°C ± 2°C /NMT 25%RH Real Time: 30°C ± 2°C / 35±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.	EXP-OP-160	PLT-OP-005	PLT-OP-006
Batch Size	500ml	1 liter	1 liter
Manufacturing Date	May – 2015	Nov-2016	Nov-2016
Date of Initiation	June-2015	Dec-2016	Dec-2016
No. of Batches	3		
Date of Submission	11-04-2018 (Dy. No. 13487)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from M/s Enaltec Labs is submitted.
		Copy of COA from M/s Indoco remedies 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 Indoco Remedies Certificate No. NEW-WHO-GMP/CERT/KD/59732/2017/11/21539 issued by Food & Drug Adminstration, M. Bandra-kurla Complex Bandra, Mumbai- 400 Maharashtra is submitted.
		Copy of GMP of Enaltec Labs Certificate No. 6078745 issued by Food & Drug Adminstration, Maharashtra 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.	No

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

- Batch no : EXP-OP-160 is manufactured from Indoco Remedies Bromfenac Sodium Sesquihydrate Batch No: RK13BRN001
- Batch no : PLT-OP-005 is manufactured from Enaltec Lab Bromfenac Sodium Batch No: EL-03/A007/13002
- Batch no : PLT-OP-006 is manufactured from Enaltec Lab Bromfenac Sodium Batch No: EL-03/A007/13002
- For Batch No: EXP-OP-160 they performed Long term stability study for 24 months while for Batch no : PLT-OP-005 & Batch no : PLT-OP-006 6 months long term stability study.
- Documents confirming import of API etc:

In reference to letter No. F.1-1/2017/PEC- DRAP (AD PEC- IV) dated :02 May, 2018 firm requested for extension

1) On 4th May, 2018 request for extension till 30 May, 2018
2) On 28th May, 2018 request for extension till July, 2018
3) On 23rd May, 2018 request for extension till 31 October, 2018
4) On 25th January, 2018 request for extension till 30 June, 2019
5) On 26th April, 2018 request for extension till 30 June, 2019

Decision: Registration board after thorough deliberation decided to reject the above applied application as firm has not submitted documents confirming import of API for conduction of stability study not submitted since more than one year.

b. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
804.	M/S Indus Pharma (Pvt) Ltd Plot No. 26, 27,63, 64, 65, 66 & 67, Sector-27, Korangi Industrial Area Karachi.	Exilant 60mg Capsule Each HPMC capsule contains: Dual Delayed Release dexlansoprazole pellets 23% eq to Dexlansoprazole …….60mg Proton Pump inhibitor (Manufacturers specifications)	Form 5 D 30-01-2018 Dy. No.3745 Rs.50,000/- 14's As per SRO	Dexilant Delayed Release Capsule 60mg of USFDA approved Last inspection was conducted on 16-08-2017 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance	Differential fee of Rs: 50000 Deposit slip No: 0742299 dated 02-07-2018 submitted for pellets.

STABILITY STUDY DATA

Drug	Exilant 60mg Capsule
Name of Manufacturer	M/S Indus Pharma (Pvt) Ltd Karachi
Manufacturer of API	M/S Murli Krishan Pharma Pvt Ltd, India

API Lot No.	MKPPLR-DEF-17001		
Description of Pack (Container closure system)	Alu/Alu		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, ,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	P-1/DEX CAPS	P-2/DEX CAPS	P-3/DEX CAPS
Batch Size	2,500 capsules	2,500 capsules	2,500 capsules
Manufacturing Date	June– 2017	June – 2017	June – 2017
Date of Initiation	15-06-2017	15-06-2017	15-06-2017
No. of Batches	3		
Date of Submission	30-01-2018 (Dy. No3745)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from M/s Murli Krishan Pharma 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 Certificate No. New-WHO-GMP/CERT/PD/52224/2017/11/18462 issued by Food & Drug administration, M.S. Bandra-Kurla Complex, Maharashtra, 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.	Copy of ADC (Karachi) attested dated: 10-10-2017 Commercial Invoice No MKPPL/RG/011 Dated: 24-05-2017 issued by M/s Murli Krishan Pharama, India 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

- Commercial Invoice of API was attested by ADC Karachi on 10-10-2017 while all the 3 batches are produced in june 2017 and stability starts on 15-06-2017 .
- **Firm reply:**
- **"**Kindly note that the request for the issuance of form6/Clearnce certificate was submitted to DRAP- Karachi in letter dated 29th May 2017 along with required document.

We further investigated the concern from your office and were informed by the respective personnel of the concern department of Indus Pharma that during the evalution of our application by Drap- Karachi, we were informed by the Pakistan customs that our consignment of Dexlansoprazole DDR pellets 23% - 2.5 Kg for the testing and trial/Developmental Batches, had been released via the Green channel by the customs on 3rd June 2017,

based on the submissionof soft copies of the essential documents on the computerized system weboc (web based one custom) of the Pakistan customs. We had the consignment cleared accordingly and was used for testing and development of trial batches in June 2017 and put on stability accordingly

As our application was al;ready filled in DRAP – Karachi, We received the Form-6 along with ADC/Ad attested commercial invoice on 10th October 2017"

- Certificate of analysis of API by manufacturer submitted is for different batch No than batch No mentioned on commercial invoice

Firm reply:

Kindly note that the batch No in certificate of analysis is a typographical error. The correct batch No is MKPPLR-DEF-17001 as mentioned in commercial invoice instead of MKPPLR-DLF-17001

Decision: The Registration Board decided to constitute the following panel for onsite investigation to confirm genuineness/ authenticity of stability data and associated documents, import of API, quality, specification, test analysis, facilities etc.

Prof. Dr. Rafeeq Alam Khan, Member Registration Board.

- Dr. Saif ur Rehman Khattak, Director/FGA, CDL, Karachi.
- Mr. Sajjad Abbasi, FID, Karachi.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Exilant 60mg (Dexlansoprazole) Capsules by M/s. Indus Pharma (Pvt.), Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (PT) dated 17th January, 2019.
Investigation Date and Time: 14th March, 2019 (Morning).
Investigation Site: Factory premises of M/s. Indus Pharma (Pvt.) Limited, Korangi Industrial Area, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Indus Pharma, Plots No. 26, 27, 63-67, Sector 27, Korangi Industrial Area, Karachi for registration of Exilant 60mg (Dexlansoprazole) 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. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board, Islamabad.
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Dr. Sajjad Abbasi, Area FID, DRAP Office, 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:

Sr. No.	Question	Observation bypanel
1.	Doyouhavedocumentsconfirmingthe import ofDexlansoprazole API including approvalfromDRAP?	Thefirmhasimported2.5kgDexlansoprazole pelletsfromM/sMurli Krishna,Indiainvoice number: MKPPL/RG/011 dated 24/05/2017.Approval fromDRAP Office,Karachi was obtained on 10/10/2017 i.e. after a period of 4 months.
2.	Whatwastherationalebehindselecting the particularmanufacturerofAPI?	There is proper vendor evaluation process being implementedincludingPostalAuditchecklist,Testingof the APIand GMP approvalbycompetentauthority along with the DMF.

3.	Do you have documents confirming the import of Dexlansoprazole reference standard and impurity standard?	The firm has document confirming the imported Dexlansoprazole pellets(API), working standard of the API and 2 major impurities from the manufacturer of the API.
4.	Do you have certificate of Analysis of the API, reference standard of the API and impurity standard?	The firm has certificate of analysis for the API, working standard of the API and 2 major impurities standards.
5.	Do youhave GMP certificate of API manufacturers issued by regulatory authoritiesofcountryoforigin?	The firm has valid GMP certificate of the API manufacturer issued by the concerned provincial Regulatory Authority of the country of origin.
6.	Do you use API manufacture rmethod of testing for testing API?	The firm has used API manufacturer method for testing API.
7.	Doyouhavestabilitystudiesreporton API?	The firmhasstabilitystudies reports on the 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 HPLC 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 the API, and working standard of API only.
11.	Have you used pharmaceutical grade excipients?	No excipients used, Only HMPC based capsule shells as used by the innovator. (Dexilant capsule manufactured by Takeda Pharma)
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipient.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipient used.
14.	Do you have written and authorized protocols for the development of Dexlansoprazole capsules?	The firm has written and authorized protocols for the development of Exilant Capsules 60mg (Dexlansoprazole).
15.	Have you performed Drug-excipient compatibilitystudies?	Same excipients were used as of innovator.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies on their capsules against the innovator product Dexilant Capsules 60mg batch no/lot no. A25777, Manufactured By: Takeda Pharma, USA). The firm's product has comparable dissolution profile with that of the innovator product.
17.	Doyouhaveproductdevelopment(R&D) section?	The firm does not have dedicated product development section.They have equipment's for manufacturing lab scale batches. Some of these equipments are used while shifting them to the commercial manufacturing area, whereas, some equipments of commercial scale manufacturing are being used for product development. Dedicated area for product development is under renovation. New small-scale equipment for R%D have arrived at the facility and will be commissioned after renovation work is completed.
18.	Do you have necessary equipment available in product development section for development of Dexlansoprazole capsules?	As above.
19.	Are the equipment in product development section qualified?	The available equipment for productdevelopment section are qualified.
20.	Do you have proper maintenance calibration/re-qualification program for the equipment used in PD section?	The firm has propermaintenance/calibration with re-Qualification program for the equipment used for product development.

21.	Do you have qualifiedstaffinproduct development section with proper knowledge and training in product development?	The firm has a team of 05 technical persons (04 Pharmacist &1 MSC Chemistry) for product development. These personnel have proper knowledge and trainining product development.
22.	Have you manufactured three stability batches for the stability studies of Dexlansoprazole capsules as required?	The firm has manufactured three stability batches of Exilant Capsules 60mg capsules having batch # P-1/DEX, P-2/DEX and P-3/ DEXeach of 2500 capsules batch size.The capsulesare packed in Alu Alu blisters of pack size 2x7s.
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the quantity of capsules required per testing frequency and the 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. All the Log Books are properly maintained.
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 fortesting of stability batches?	The method is based upon the API method of API manufacturer. The firm has fully validated the method for testing of their finished product.
27.	Doyouhavemethodtransferstudiesin casewhenthemethodoftestingbeing usedbyyourfirmisgivenbyanyother lab?	The firmhasperformed complete validation studies.
28.	Do you have documents confirming the qualification of equipments/instruments being used in the test and analysis of Dexlansoprazole API and the finished drug?	The firm has proper documents confirming the qualificationofequipment/instrumentsbeingusedinthe testandanalysis ofthe APIand the finished drug.
29.	Do your method of analysis stability indicating?	The firm has performed forced degradation (FD) study on their product Exilant Capsules 60mg capsules for the conformance of stability indicating nature of their method for testing the finished product during stability studies.
30.	Do your HPLC software 21CFR Compliant?	1. Yes, HPLC software is 21 CFR Part 11 compliant where all user levels are properly defined. 2. No user or main user can delete, edit or manipulate data from software. 3. All actions are recorded in audit trails. 4. Created strict policies on windows and disable options like "Delete, Copy, Paste and rename" of any file from user level. Furthermore, the following improvements are being made in order to strengthen it further. 1. A new HPLC of "Agilent Infinity series" has been installed in Quality Control Laboratory & two more are under procurement and will be commissioned by the mid of 2019. 2. Chromatography Data System (CDS) Software is also being procured for Compliance and Data Security. With the ever-evolving emphasis on data security, data integrity, and compliance, it is of vital importance that the software provides comprehensive preventive and detection technical controls. This will enable us to meet the latest regulatory requirements and ensure the highest levels of data quality.
31.	Can you showAudit trail reports on Dexlansoprazoletesting?	Audittrailonthetestingreports is available.

32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches only.
33.	Do you have stability batches kept on stability testing?	The firm has three stability batches kept on realtime stability testing. 18months studies have been completed on these batches with satisfactory results.
34.	Do you have valid calibration status for the equipments used in Dexlansoprazole capsules production and analysis?	The firm has valid calibration status for the equipment used in Exilant Capsules 60mg production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequatemonitoringandcontrolareavailableforstability chambers including data loggers and centralized controllingsoftware.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Exilant 60mg (Dexlansoprazole) Capsules is verifiable to satisfactory level .
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited For the manufacturing of Exilant 60mg (Dexlansoprazole) Capsules.

Recommendations:

1. Since Exilant 60mg Capsules are modified release (delayed release) capsules therefore, post registration Bioequivalence studies should be conducted on the product before marketing.
2. Firm must developed specific identification test for dexlansoprazole in the pallets and the finished product .
3. The firm may kindly be granted necessary registration of Exilant 60mg (Dexlansoprazole) Capsules.

Note: The firm has submitted written undertaking for post registration bioequivalence studies on the capsules (copy enclosed

Decision: Deferred for following reason:

- **Commercial Invoice of API was attested by DRAP Karachi on 10-10-2017 while all the 3 batches are produced in june 2017 and stability starts on 15-06-2017 .**
- **Recommendation by panel that "Firm must developed specific identification test for dexlansoprazole in the pellets and the finished product"**

c. Exemption from onsite verification of stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date	Remarks
805.	M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad	Voreta Tablets 10 mg Each Film Coated tablet contains: Empagliflozin ……10mg Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor. (Manufacturer's Specification)	Form 5 Dairy No.4415 Dated:31-01-2019 Rs.20,000/- dated: 31-01-2019 1x10's, 1x14's, 2x7's, 4x7's, 3x10's, 30's, 2x10's; As per SRO	Jardiance Tablets 10 mg by Boehringer Ingelheim Pharmaceuticals, USFDA GMP Inspection conducted on 10-10-2018 & 17-10-2018 concluded that the panel unanimously recommended for the grant of cGMP certificate.	

STABILITY STUDY DATA			
Drug	Voreta Tablets 10 mg		
Name of Manufacturer	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co. Ltd., China		
API Lot No.	D5284-17-004		
Description of Pack (Container closure system)	Alu Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH 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) Real Time: 0, 3,6, (months)		
Batch No.	Trial # 01	Trial # 01	Trial # 01
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	02/2018	02/2018	02/2018
Date of Initiation	15/2/2018	15/2/2018	15/2/2018
No. of Batches	03		
Date of Submission	30-01-2019 (4213)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA (Batch#D5284-17-004) from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate (certificate No.ZJ20140072) issued by China Food & Drug Administration China. It is valid until 25/09/2019.
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 Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC DRAP (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd and Copy of Commercial Invoice (invoice No. HH20171596, dated: 17-07-2017) attested by ADC DRAP (Islamabad) dated 27-07-2017 is also 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		
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 onsite inspection report of their product Dascot Tablets 30mg and 60 mg and Velscot 400mg/100mg tablets which was conducted on 26th January, 2018 and was presented in 278th meeting of Registration Board held on 29-31st January, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
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 Drap (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd China and Copy of Commercial Invoice (invoice No. HH20171596, dated: 17-07-2017) attested by ADC Drap (Islamabad) dated 27-07-2017 are submitted.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted photocopy of Invoices for the procurement of reference standard and impurity standards.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted GMP Certificate No: ZJ20140072 from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted. Issued by China Food & Drug Administration China. It is valid until 25/09/2019.
5.	Mechanism for Vendor pre-qualification	The firm has submitted photocopy of "SOP for Selection of manufacturer for API/Excipient and Procurement Procedure.
6.	Certificate of analysis of the API, reference standards and impurity standards	The firm has submitted COA of API Batch No.D5284-17-004 COA of Reference Std Batch No. 2015-583 COA of Empagliflozin Ethoxy Impurties Batch No.2016-1024
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
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted photocopy of List of qualified staff involved in product development
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of Development Protocol for Lab scale batch manufacturing of Voreta tablets 10mg.

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<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports for all excipients used in product development of Voreta 10 mg tablets.</td></tr>
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<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product (Voreta Tablets) with Innovator’s Brand “Jardiance Tablets” The details are as follows:
<table><tr><td>Feature</td><td>Reference. Product</td></tr><tr><td>Brand Name</td><td>Jardiance Tablets 10mg</td></tr><tr><td>Batch No.</td><td>607110</td></tr><tr><td>Mfg. Date</td><td>09/2016</td></tr><tr><td>Exp. Date</td><td>09/2019</td></tr></table>Comparative dissolution studies have been performed in following media:</td></tr>
</table>

		i. pH 1.2 HCl solution. ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. 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.	Firm has submitted audit trail reports for complete stability studies analysis of three batches, comparative dissolution and method of testing.
	Remarks of Evaluator:	

Decision: Registration Board decided to approve registration of "Voreta Tablets 10 mg (Empagliflozin)" with Innovator's specifications by M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, 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 GMP Inspection Report Date
806.	M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad	Voreta Tablets 25 mg Each Film Coated tablet contains: Empagliflozin….25mg Anti-DiabeticDrug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor. (Manufacturer's Specification)	Form 5 Dairy No.4416 Dated: 31-01-2019 Rs.20,000/- dated 31-01-2019 1x10's, 1x14's, 2x7's, 4x7's, 3x10's, 30's, 2x10's; As per SRO	Jardiance Tablets 25 mg by Boehringer Ingelheim Pharmaceuticals, USFDA GMP Inspection conducted on 10-10-2018 & 17-10-2018 concluded that the panel unanimously recommended for the grant of cGMP certificate.

STABILITY STUDY DATA

Drug	Voreta Tablets 25 mg		
Name of Manufacturer	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co. Ltd., China		
API Lot No.	D5284-17-004		
Description of Pack (Container closure system)	Alu Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH 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) Real Time: 0, 3,6, (months)		
Batch No.	B# T-01	B# T-02	B# T-03
Batch Size	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	02/2018	02/2018	02/2018
Date of Initiation	11/2/2018	11/2/2018	11/2/2018
No. of Batches	03		
Date of Submission	30-01-2019 (4214)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA (Batch#D5284-17-004) from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate (certificate No.ZJ20140072) issued by China Food & Drug Administration China. It is valid until 25/09/2019.
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 Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC DRAP (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd and Copy of Commercial Invoice (invoice No. HH20171596, dated: 17-07-2017) attested by ADC DRAP (Islamabad) dated 27-07-2017 is also 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

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 onsite inspection report of their product Dascot Tablets 30mg and 60 mg and Velscot 400mg/100mg tablets which was conducted on 26th January, 2018 and was presented in 278th meeting of Registration Board held on 29-31st January, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
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 Drap (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd China and Copy of Commercial Invoice (invoice

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COA of API Batch No.D5284-17-004
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COA of Empagliflozin Ethoxy Impurties
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		analysis of APIs (Empagliflozin) 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 Voreta Tablets 25mg. 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.	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 Empagliflozin from Zhejiang Huahai Pharmaceuticals CO; Ltd China.
16.	Analysis reports for excipients used.	The firm has submitted copies of Analytical reports for all excipients used in product development of Voreta 25 mg tablets.
17.	Drug-excipients compatibility studies.	The firm has stated that we manufactured lab scale batches of our applied products "Voreta Tablets" by using same formulation (excipients) of Innovator's Product.
18.	Record of comparative dissolution data.	Firm has submitted Comparative dissolution study of their product (Voreta Tablets) with Innovator's Brand "Jardiance Tablets" The details are as follows: Feature: Reference. Product Brand Name: Jardiance Tablets 25mg Batch No.: 605049 Mfg. Date: 06/2016 Exp. Date: 06/2019 Comparative dissolution studies have been performed in following media: i. pH 1.2 HCl solution. ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. 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.	Firm has submitted audit trail reports for complete stability studies analysis of three batches, comparative dissolution and method of testing.
	Remarks of Evaluator:	

Decision: Registration Board decided to approve registration of "Voreta Tablets 25 mg (Empagliflozin)" with Innovator's specifications by M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, 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 GMP Inspection Report Date
807.	M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad	Voreta Plus Tablets 12.5 mg/500 mg Each film coated tablet contains: Empagliflozin.....12.5 mg Metformin HCl.....500 mg	Form 5D Dairy No. 42033 dated Rs.50,000/- dated 07-12-2018	Synjardy Tablets 12.5 mg/500 mg by Boehringer Ingelheim Pharmaceuticals, USFDA GMP Inspection conducted on 10-10-2018 & 17-10-2018

		Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor. (Manufacturer's Specification)	1x10's, 3x10's, 6x10's, 8x10's; As per SRO	concluded that the panel unanimously recommended for the grant of cGMP certificate.

STABILITY STUDY DATA			
Drug	Voreta Plus Tablets 12.5 mg/500 mg		
Name of Manufacturer	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co. Ltd., China **Metformin HCl:** M/s Abhilasha Pharma Pvt. Ltd India		
API Lot No.	**Empagliflozin:** D5284-17-004 **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 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) Real Time: 0, 3,6, (months)		
Batch No.	B# T-01	B# T-02	B# T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11/2017	11/2017	11/2017
Date of Initiation	20/11/2017	20/11/2017	20/11/2017
No. of Batches	03		
Date of Submission	26-02-2019 (8554)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	**Empagliflozin:** Copy of COA (Batch#D5284-17) from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted.
		Metformin hydrochloride: Copy of COA (Batch# MET123/17) from M/s Abhilasha Pharma 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.	**Empagliflozin:** Copy of GMP Certificate (certificate No.ZJ20140072) issued by China Food & Drug Administration China. It is valid until 25/09/2019.
		Metformin hydrochloride: Copy of GMP certificate (Certificate No. 1706138) issued by Food & Drugs Control Administration, Gandhinagar, Gujarat state, India for M/s Abhilasha Pharma Pvt. Ltd India. It is valid upto 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.	**Empagliflozin:** Copy of Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC DRAP (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd and Copy of Commercial Invoice (invoice No. HH20171596) attested by ADC DRAP (Islamabad) dated 27-07-2017 is also submitted.
		Metformin HCl: Copy of Export invoice (Invoice No. Exp009)) issued by ADC DRAP (Islamabad) dated 06-09-2017, for the import of Metformin HCl from M/s Abhilasha Pharma Pvt. Ltd India
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

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 onsite inspection report of their product Dascot Tablets 30mg and 60 mg and Velscot 400mg/100mg tablets which was conducted on 26th January, 2018 and was presented in 278th meeting of Registration Board held on 29-31st January, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Empagliflozin:** Copy of Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC Drap (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd China and Copy of Commercial Invoice (invoice No. HH20171596) attested by ADC Drap (Islamabad) dated 27-07-2017 are submitted.
		Metformin HCl: Copy of Export invoice (Invoice No. Exp009)) issued by ADC DRAP (Islamabad) dated 06-09-2017, for the import of Metformin HCl from M/s Abhilasha Pharma Pvt. Ltd India.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted photocopy of Invoices for the procurement of reference standard and impurity standards.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** The firm has submitted GMP from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted. Issued by China Food & Drug Administration China. It is valid until 25/09/2019.

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<tr><td></td><td></td><td>Metformin HCl: The firm has submitted GMP from M/s Abhilasha Pharma Pvt. Ltd India issued by Food & Drugs Control Administration, Gandhinagar, Gujarat state, India. It is valid upto 01-06-2019.</td></tr>
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COA of API Batch No.D5284-17-004
COA of Reference Std Batch No. 2015-583
COA of Empagliflozin Ethoxy Impurties
Batch No.2016-1024</td></tr>
<tr><td>Metformin HCl: The firm has submitted
COA of API Batch No. MET123/17
COA of Reference Std Batch No. RO69HO
COA of Dicyandiamide (Impurity A)
Batch No.RM083/17</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 Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
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<tr><td rowspan="2">13.</td><td rowspan="2">Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs (Empagliflozin) along with COA.</td></tr>
<tr><td>The firm has submitted photocopy of method used for analysis of APIs (Metformin HCl) along with COA.</td></tr>
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<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 Voreta Plus Tablets 12.5 mg/500 mg.
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 rowspan="2">15.</td><td rowspan="2">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, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Empagliflozin from Zhejiang Huahai Pharmaceuticals CO; Ltd China.</td></tr>
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<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports for all excipients used in product development of Voreta Plus Tablets 12.5 mg/500 mg.</td></tr>
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<table>
<tr><td>Feature</td><td>Reference. Product</td></tr>
<tr><td>Brand Name</td><td>Synjardy Tablets 12.5 mg/500 mg</td></tr>
<tr><td>Batch No.</td><td>857718</td></tr>
<tr><td>Exp. Date</td><td>04/2021</td></tr>
</table>
Comparative dissolution studies have been performed in following media:
i. pH 1.2 HCl solution.
ii. pH 4.5 Acetate buffer solution.
iii. pH 6.8 phosphate buffer solution.
Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies..</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 complete stability studies analysis of three batches, comparative dissolution and method of testing.</td></tr>
<tr><td></td><td>Remarks of Evaluator:</td><td></td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “Voreta Plus Tablets (Empagliflozin 12.5mg, Metformin HCl 500 mg)” with Innovator’s specifications by M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, 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.</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 GMP Inspection Report Date	Remarks
808.	M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad	Voreta Plus Tablets 5mg/1000mg Each Film Coated Tablet contains: Empagliflozin……5mg Metformin HCl...1000mg Anti-Diabetic Drug, Sodium-Glucose Co-Transporter2 (SGLT2) Inhibitor (Manufacturer's Specification)	Form 5D Dairy No. 42032 Dated; 07-12-2018 Rs.50,000/- dated 07-12-2018 1x10's, 3x10's, 6x10's, 8x10's; As per SRO	Synjardy Tablets 5 mg/1000 mg by Boehringer Ingelheim Pharmaceuticals, USFDA GMP Inspection conducted on 10-10-2018 & 17-10-2018 concluded that the panel unanimously recommended for the grant of cGMP certificate.	

STABILITY STUDY DATA

Drug	Voreta Plus Tablets 5 mg/1000 mg		
Name of Manufacturer	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	**Empagliflozin:** M/s Zhejiang Huahai Pharmaceutical Co. Ltd., China **Metformin HCl:** M/s Abhilasha Pharma Pvt. Ltd India		
API Lot No.	**Empagliflozin:** D5284-17-004 **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 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) Real Time: 0, 3,6, (months)		
Batch No.	B# T-01	B# T-02	B# T-03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	11/2017	11/2017	11/2017
Date of Initiation	13/11/2017	13/11/2017	13/11/2017
No. of Batches	03		
Date of Submission	26-02-2019 (8553)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	**Empagliflozin:** Copy of COA (Batch#D5284-17) from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted.

		Metformin hydrochloride: Copy of COA (Batch# MET123/17) from M/s Abhilasha Pharma 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.	**Empagliflozin:** Copy of GMP Certificate (certificate No.ZJ20140072) issued by China Food & Drug Administration China. It is valid until 25/09/2019.
		Metformin hydrochloride: Copy of GMP certificate (Certificate No. 1706138) issued by Food & Drugs Control Administration, Gandhinagar, Gujarat state, India for M/s Abhilasha Pharma Pvt. Ltd India. It is valid upto 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.	**Empagliflozin:** Copy of Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC DRAP (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd and Copy of Commercial Invoice (invoice No. HH20171596) attested by ADC DRAP (Islamabad) dated 27-07-2017 is also submitted.
		Metformin HCl: Copy of Export invoice (Invoice No. Exp009)) issued by ADC DRAP (Islamabad) dated 06-09-2017, for the import of Metformin HCl from M/s Abhilasha Pharma Pvt. Ltd India
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

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 onsite inspection report of their product Dascot Tablets 30mg and 60 mg and Velscot 400mg/100mg tablets which was conducted on 26th January, 2018 and was presented in 278th meeting of Registration Board held on 29-31st January, 2018. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.

<table>
<tr><td rowspan="2">2.</td><td rowspan="2">Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Empagliflozin: Copy of Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC Drap (Islamabad) dated 14-07-2017, for the import of Empagliflozin from M/s Zhejiang Huahai Pharmaceuticals CO; Ltd China and Copy of Commercial Invoice (invoice No. HH20171596) attested by ADC Drap (Islamabad) dated 27-07-2017 are submitted.</td></tr>
<tr><td>Metformin HCl: Copy of Export invoice (Invoice No. Exp009)) issued by ADC DRAP (Islamabad) dated 06-09-2017, for the import of Metformin HCl from M/s Abhilasha Pharma Pvt. Ltd India.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted photocopy of Invoices for the procurement of reference standard and impurity standards.</td></tr>
<tr><td rowspan="2">4.</td><td rowspan="2">Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Empagliflozin: The firm has submitted GMP from M/S Zhejiang Huahai pharmaceuticals CO; Ltd China is submitted. Issued by China Food & Drug Administration China.
It is valid until 25/09/2019.</td></tr>
<tr><td>Metformin HCl: The firm has submitted GMP from M/s Abhilasha Pharma Pvt. Ltd India issued by Food & Drugs Control Administration, Gandhinagar, Gujarat state, India.
It is valid upto 01-06-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for Selection of manufacturer for API/Excipient and Procurement Procedure.</td></tr>
<tr><td rowspan="2">6.</td><td rowspan="2">Certificate of analysis of the API, reference standards and impurity standards</td><td>Empagliflozin: The firm has submitted
COA of API Batch No.D5284-17-004
COA of Reference Std Batch No. 2015-583
COA of Empagliflozin Ethoxy Impurties
Batch No.2016-1024</td></tr>
<tr><td>Metformin HCl: The firm has submitted
COA of API Batch No. MET123/17
COA of Reference Std Batch No. RO69HO
COA of Dicyandiamide (Impurity A)
Batch No.RM083/17</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 Purchase Order/Invoices for the 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>The firm has submitted photocopy of List of qualified staff 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 photocopy of Development Protocol for Lab scale batch manufacturing of Voreta Plus Tablets 12.5 mg/500 mg.</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 of the following 03 Batches
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>T#01</td><td>1500 Tablets</td><td>11-2017</td></tr>
<tr><td>T#02</td><td>1500 Tablets</td><td>11-2017</td></tr>
<tr><td>T#03</td><td>1500 Tablets</td><td>11-2017</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches.
The detail is as under:
<table><tr><th>Trial no.</th><th>Total no. of tablets for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr><tr><td>01</td><td>480 tabs</td><td>220 tabs</td><td>256 tabs</td></tr><tr><td>02</td><td>480 tabs</td><td>220 tabs</td><td>256 tabs</td></tr><tr><td>03</td><td>480 tabs</td><td>220 tabs</td><td>256 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 copy of record of digital data logger for temperature and humidity monitoring of stability chambers from Nov.2017 to June.2018.</td></tr>
<tr><td rowspan="2">13.</td><td rowspan="2">Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs (Empagliflozin) along with COA.</td></tr>
<tr><td>The firm has submitted photocopy of method used for analysis of APIs (Metformin HCl) 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 Voreta Plus Tablets 5mg/1000 mg.
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 rowspan="2">15.</td><td rowspan="2">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, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Empagliflozin from Zhejiang Huahai Pharmaceuticals CO; Ltd China.</td></tr>
<tr><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) &long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Metformin HCl from M/s Abhilasha Pharma Pvt. Ltd India.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of Analytical reports for all excipients used in product development of Voreta Plus Tablets 5 mg/1000 mg.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has stated that we manufactured lab scale batches of our applied products “Voreta Plus Tablets 5mg/1000 mg” by using same formulation (excipients) of Innovator’s Product.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product (Voreta Plus Tablets 5 mg/1000 mg) with Innovator’s Brand “Synjardy Tablets 5 mg/1000 mg” The details are as follows:
<table><tr><td>Feature</td><td>Reference. Product</td></tr><tr><td>Brand Name</td><td>Synjardy Tablets 5mg/1000 mg</td></tr><tr><td>Batch No.</td><td>856298</td></tr><tr><td>Exp. Date</td><td>02/2021</td></tr></table>Comparative dissolution studies have been performed in following media:
i. pH 1.2 HCl solution.</td></tr>
</table>

		ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. 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.	Firm has submitted audit trail reports for complete stability studies analysis of three batches, comparative dissolution and method of testing.
	Remarks of Evaluator:	

Decision: Registration Board decided to approve registration of "Voreta Plus Tablets (Empagliflozin 5mg, Metformin HCl 1000 mg)" with Innovator's specifications by M /s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, 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 GMP Inspection Report Date	Remarks
809.	M/s Shaigan Pharmaceuticals , 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Dacavir-60 Tablets Each Film coated Tablet Contains: Daclatasvir Dihydrochloride ……....60mg Direct Acting Antivirals (Antivirals for treatment of HCV infections) Manufacturer's Specifications.	Form 5-D Dairy No. Duplicate Dossier Rs.50,000/-, 22-12-2016 (Duplicate) As per SRO	DAKLINZA daclatasvir tablets by M/s Gilead Sciences, Inc (USFDA approved) 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	Dacavir 60 Tablets		
Name of Manufacturer	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi		
Manufacturer of API	Ruyuan HEC Pharma Co .Ltd China		
API Lot No.	DSV-RD201602201R1		
Description of Pack (Container closure system)	Alu-Alu Blister of 4x7'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 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-001	T-001
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets

Manufacturing Date	03-2017	03-2017	03-2017
Date of Initiation	29-03-2017	29-03-2017	29-03-2017
No. of Batches	03		
Date of Submission	28-01-2019 (3661)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# DSV-RD201602201R1) from Ruyuan HEC Pharma 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 issued by Shaoguan Food and Drug Administration Peoples Republic of China (Certificate #2018004), has been submitted with validity till 05-03-2019.
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 700g of Daclatasvir (Invoice#W20160216PK0103) attested by ADC DRAP, Islamabad dated 13-05-2016.
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

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.	The firm has submitted reference of already approved product in 285th meeting the decision as: 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. **Date of inspection**: 8th August, 2018 The HPLC software of the firm is 21 CRF compliant. 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 700g of Daclatasvir (Invoice#W20160216PK0103) attested by ADC DRAP, Islamabad dated 13-05-2016.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has stated that Reference standards and impurity standard were supplied free of cost therefore Import Documents are unavailable, whereas COA of both are submitted.</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 Shaoguan Food and Drug Administration Peoples Republic of China (Certificate #2018004), has been submitted with validity till 05-03-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor prequalification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA of Daclatasvir ((Batch# DSV-RD201602201R1) from Ruyuan HEC Pharma Co .Ltd China, is submitted.
• Copy of COA of working standards Batch# PRS-15048 have been Submitted
• COAs of impurity standards have been submitted.
Impurity A (Batch# PRS-16043)
Impurity B (Batch# PRS-16044)
Impurity C (Batch# PRS-16022)</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 “Dacavir 60 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>03-2017</td></tr>
<tr><td>T-002</td><td>1000 Tablets</td><td>03-2017</td></tr>
<tr><td>T-003</td><td>1000 Tablets</td><td>03-2017</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 Qty of tablets</th></tr>
<tr><td>T-001</td><td>868</td><td rowspan="3">638</td><td>230</td></tr>
<tr><td>T-002</td><td>870</td><td>232</td></tr>
<tr><td>T-003</td><td>863</td><td>225</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 from 20-03-2017 to 11-10-2017 and Real Time stability chamber starting from 24-03-2017 to 02-10-2017.</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 Daclatasvir.</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 “Dacavir-60 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 (40°C±2°C/75%±5%RH) and 36 Months Real Time (30°C±2°C/65%±5%RH) Stability Study Data of 03 Batches for Daclatasvir from Ruyuan HEC Pharma Co .Ltd China.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that ingredients of Dacavir-60 Tablets and Daklinza 600mg Tablet (innovator brand) are same.</td></tr>
</table>

18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies with Mydekla 60mg Tablets manufactured by M/s. Mylan Labs, India (Batch#8067665, EXP 04/19) using Phosphate buffer pH 6.8 with 0.7% Brij 35. The firm's product (Dacavir 60 Tablets) results are comparable with MYDEKLA 60mg Tablets.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Dacavir-60 Tablets from 13-04-2017 to 28-09-2018.
	Remarks of Evaluator:	

Decision: Registration Board decided to approve registration of "Dacavir-60 Tablets (Daclatasvir Dihydrochloride)" with Innovator's specifications by M/s Shaigan Pharmaceuticals , 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.

810.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	SILOS 4mg Capsules
	Composition	Each capsules contains: Silodosin MS……4mg
	Diary No. Date of R& I & fee	Dy NO.113921; 05-03-2019: 50,000/- (04-03-2019)
	Pharmacological Group	Antiadrenergic agent
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	10's: RS; 600-/10's
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (RAPAFLO Capsules of ALLERGAN SALES LLC)
	Me-too status	N/A
	GMP status	GMP certificate issued dated: 14-06-2018

STABILITY STUDY DATA

Drug	SILOS 4mg Capsules		
Name of Manufacturer	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.		
Manufacturer of API	M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China		
API Lot No.	Lot#: 13000-171203-02-1 , Quantity; 1kg		
Description of Pack (Container closure system)	Alu/Alu		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH	Real Time: 30°C ± 2°C/65%±5% RH	
Time Period	Accelerated: 6 (Months)	Real Time: 6 (Months)	
Frequency	Accelerated: 0,1,2,3,4,6 (Months)	Real Time: 0,3,6,9,12,18,24 (Months)	
Batch No.	Lab#01	Lab#02	Lab#03
Batch Size	4000 Capsules	4000 Capsules	4000 Capsules
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	June 2018	June 2018	June 2018
No. of Batches	03		
Date of Submission	05-03-2019 (11391)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch#13000-171203-02-1) from M/S Zhejiang Tianyu Pharmaceuticals Co., Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	Copy of GMP (certificate no. MI-2016-CE-06202-1) has been submitted for M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China approved by TGA, Austraila .Valid till 15-03-2021

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 License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 12-02-2018, for the import of Silodosin API from M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China; has been submitted. Copy of Commercial invoice No. TYI18106 attested by ADC (Karachi) dated 12-02-2018 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

REMARKS OF EVALUATORS

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION ROM 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:

ADMINISTRATION PORTION

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years- DELANZO DR (Dexlansoprazole) 30mg & 60mg Capsules on 02nd April, 2018, by following panel: 1. Prof. Dr. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Woman, 5-C, St-1, Nazimabad, Karachi 2. Dr. Saif-Ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi. 3. Dr. Mehwish Tanveer, Assistant Director, DRAP Office, Karachi. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers
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 12-02-2018, for the import of Silodosin API from M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China; has been submitted. Copy of Commercial invoice No. TYI18106 attested by ADC (Karachi) dated 12-02-2018 has been submitted
3.	Documents for the procurement of reference standard and impurity standards.	Impurity and working standards were also dispatched with API
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP (certificate no. MI-2016-CE-06202-1) has been submitted for M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China approved by TGA, Austraila .Valid till 15, March 2021

<table>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Work instruction for Evaluation of Suppliers and vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of Silodosin (Batch No.#13000-171203-02-1) from M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China.
• Copy of COA of working standards Batch# WRS161201 & Batch# WRS160701 have been submitted.
• COAs of impurity standards have been submitted.
YDL Impurity 1 Batch No # IRS160901
YDL Impurity 2 Batch No # IRS160101
YDL Impurity 3 Batch No # IRS161101
YDL Impurity 4 Batch No # WRS160701</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 & COAs of all the excipients used in formulation of SILOS 4mg Capsules, from relevant manufacturers</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted copy of List of qualified staff their 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 photocopy of SOP for development of SILOS 4mg Capsules Stability protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Batch manufacturing Record of the following 3 batches Three stability batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Lab-01</td><td>4000 Capsules</td><td>May 2018</td></tr>
<tr><td>Lab-02</td><td>4000 Capsules</td><td>May 2018</td></tr>
<tr><td>Lab-03</td><td>4000 Capsules</td><td>May 2018</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 remaining quantity of three trial batches.
The detail is as under:
<table>
<tr><th>Trial no.</th><th>Total No. of Capsules for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr>
<tr><td>01</td><td>2980</td><td>416</td><td>2564</td></tr>
<tr><td>02</td><td>2980</td><td>416</td><td>2564</td></tr>
<tr><td>03</td><td>2980</td><td>416</td><td>2564</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 supplier’s method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.</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 specification & Test method along with analytical method validation report.
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(40°C ± 2°C & 75±5%RH) and 12 Months Real Time Stability Study (30°C ± 2°C & 65±5%RH) Data of 03 Batches of API M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China</td></tr>
</table>

<table>
<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 of SILOS 4mg Capsules</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Compatibility study report (dated 5-6-2018) along with raw data sheets and relevant chromatograms. It is pertinent to mention here that compatibility studies have been performed after the initiation of stability studies</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>Feature</th><th>Reference Product</th><th>Product of M/s SAMI</th></tr>
<tr><td>Brand Name</td><td>RAPAFLO</td><td>SILOS Capsules</td></tr>
<tr><td>Batch No.</td><td>1132872A</td><td>LAB-01</td></tr>
<tr><td>Exp. Date</td><td>Feb-2019</td><td>26-05-2018</td></tr>
</table>
Firm have comparable dissolution profile with the reference 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 for complete stability studies analysis of three batches.</td></tr>
<tr><td colspan="3">Remarks of Evaluator:</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “SILOS 4mg Capsules (Silodosin)” with Innovator’s specifications by M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 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>

811.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	SILOS 8mg Capsules
	Composition	Each capsules contains: Silodosin MS……8mg
	Diary No. Date of R& I & fee	Dy No.11392; 05-03-2019: 50,000/- (04-03-2019)
	Pharmacological Group	Antiadrenergic agent
	Type of Form	Form-5D
	Finished product Specification	Innovator’s Specification
	Pack size & Demanded Price	10’s; Rs: 1000/10’s
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (RAPAFLO Capsules of ALLERGAN SALES LLC)
	Me-too status	N/A
	GMP status	GMP certificate issued dated: 14-06-2018

STABILITY STUDY DATA

Drug	SILOS 8mg Capsules		
Name of Manufacturer	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.		
Manufacturer of API	M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China		
API Lot No.	Lot#: 13000-171203-02-1 , Quantity; 1kg		
Description of Pack (Container closure system)	Alu/Alu		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Lab#01	Lab#02	Lab#03
Batch Size	3000 Capsules	3000 Capsules	3000 Capsules
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	June 2018	June 2018	June 2018

No. of Batches	03	
Date of Submission	(11392) 05-03-2019	
DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA (Batch#13000-171203-02-1) from M/S Zhejiang Tianyu Pharmaceuticals Co., Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin	Copy of GMP (certificate no. MI-2016-CE-06202-1) has been submitted for M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China approved by TGA, Austraila .Valid till 15-03-2021
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 License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 12-02-2018, for the import of Silodosin API from M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China; has been submitted. Copy of Commercial invoice No. TYI18106 attested by ADC (Karachi) dated 12-02-2018 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
REMARKS OF EVALUATORS		
The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.		
REQUEST OF EXEMPTION ROM 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:		
Administration portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred last onsite panel inspection for instant dosage form conducted during last two years- DELANZO DR (Dexlansoprazole) 30mg & 60mg Capsules on 02nd April, 2018, by following panel: 1. Prof. Dr. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Woman, 5-C, St-1, Nazimabad, Karachi 2. Dr. Saif-Ur-Rehman Khattak, Director / FGA, CDL, DRAP, Karachi. 3. Dr. Mehwish Tanveer, Assistant Director, DRAP Office, Karachi. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Form 6 License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 12-02-2018, for the import of Silodosin API from M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China; has been submitted
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<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Impurity and working standards were also dispatched with API</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 no. MI-2016-CE-06202-1) has been submitted for M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China approved by TGA, Austraila .Valid till 15, March 2021</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Work instruction for Evaluation of Suppliers and vendors.</td></tr>
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• Copy of COA of working standards Batch# WRS161201 & Batch# WRS160701 have been submitted.
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YDL Impurity 1 Batch No # IRS160901
YDL Impurity 2 Batch No # IRS160101
YDL Impurity 3 Batch No # IRS161101
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<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted commercial invoices & COAs of all the excipients used in formulation of SILOS 8mg Capsules, from relevant manufacturers</td></tr>
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<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Lab-01</td><td>3000 Capsules</td><td>May 2018</td></tr>
<tr><td>Lab-02</td><td>3000 Capsules</td><td>May 2018</td></tr>
<tr><td>Lab-03</td><td>3000 Capsules</td><td>May 2018</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 remaining quantity of three trial batches.
The detail is as under:
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<tr><th>Trial no.</th><th>Total no. of Capsules for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr>
<tr><td>01</td><td>2514</td><td>336</td><td>2178</td></tr>
<tr><td>02</td><td>2514</td><td>336</td><td>2178</td></tr>
<tr><td>03</td><td>2514</td><td>336</td><td>2178</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>
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<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has supplier’s method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.</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 specification & Test method along with analytical method validation report.
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(40°C ± 2°C & 75±5%RH) and 12 Months Real Time Stability Study (30°C ± 2°C & 65±5%RH) Data of 03 Batches of API M/s. Zhejiang Tianyu Pharmaceuticals Co., Ltd. China</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 of SILOS 8mg Capsules</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Compatibility study report (dated 07-12-2018) along with raw data sheets and relevant chromatograms.
It is pertinent to mention here that compatibility studies have been performed after the initiation of stability studies</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>Feature</th><th>Reference Product</th><th>Product of M/s SAMI</th></tr>
<tr><td>Brand Name</td><td>RAPAFLO</td><td>SILOS Capsules</td></tr>
<tr><td>Batch No.</td><td>1145668M</td><td>LAB-01</td></tr>
<tr><td>Exp. Date</td><td>Feb-2019</td><td>26-05-2018</td></tr>
</table>
Firm have comparable dissolution profile with the reference 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 for complete stability studies analysis of three batches.</td></tr>
<tr><td colspan="3">Remarks of Evaluator:</td></tr>
<tr><td colspan="3">Decision:Registration Board decided to approve registration of “SILOS 8mg Capsules (Silodosin)” with Innovator’s specifications by M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 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>

812.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	IBURO 400mg/100ml Infusion
	Composition	Each 100ml contains: Ibuprofen BP ……400mg
	Diary No. Date of R& I & fee	Dy No.15669; 07-03-2019: 50,000/- (04-03-2019)
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5D
	Finished product Specification	Innovator’s Specification
	Pack size & Demanded Price	100ml
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 600mg/100ml Infusion of MHRA approved
	Me-too status	N/A

	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP.
	Remarks of the Evaluator	Both SVP and LVP sections are present.

STABILITY STUDY DATA			
Drug	IBURO 400mg/100ml Infusion		
Name of Manufacturer	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.		
Manufacturer of API	SI Group ,Orangeburg, SC, USA		
API Lot No.	Lot#: 4050-3159 , Quantity; 5 kg		
Description of Pack (Container closure system)	Glass bottle USP Type – II		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Lab#01	Lab#02	Lab#03
Batch Size	15 L	15 L	15 L
Manufacturing Date	07-2018	07-2018	07-2018
Date of Initiation	July 2018	July 2018	July 2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA (Batch#4050-3159) from M/S SI Group ,Orangeburg, SC, USA 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	SI Group, Inc. ,725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA)
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 Invoice No:442831 Ibuprofen 40 Microns ADC Attested Invoice dated: 09-10-2017 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 EVALUATORS

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION ROM 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:

Administration portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last	• Firm has referred last onsite panel inspection for instant dosage form conducted during last two years IBURO

<table>
<tr><td></td><td>two years.</td><td>(Ibuprofen) 800mg/8ml Injection on 28th January, 2019 by following panel:
1. Dr. Rafeeq Alam Khan, Meritorious Professor, Member Registration Board
2. Mr. Aslam Shah, Member Registration Board.
3. Mr. Affan Ali Qureshi, Assistant Director (CDL), DRAP, Karachi.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Form 6 License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 09-10-2017, for the import of Ibuprofen from M/s. SI Group, Inc., 725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA)
Copy of Commercial invoice No. 442831 dated 05-09-2017 attested by ADC (Karachi) dated 09-10-2017 has been submitted .</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted pro forma of Working /reference standard from EDQM.</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>SI Group, Inc., 725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA) Registration of Establishment No. 3011012288</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Work instruction for Evaluation of Suppliers and vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has Certificate of Analysis for API, working standards and impurity standard.</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 & COAs of all the excipients used in formulation of IBURO 400mg/100ml Infusion, from relevant manufacturers</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted copy of List of qualified staff their involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for development & stability testing of trial batches.</td><td>The firm has submitted photocopy of SOP for development of IBURO 400mg/100ml Infusion Stability protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Batch manufacturing Record of the following 3 batches Three stability batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Lab-01</td><td>15 L</td><td>July 2018</td></tr>
<tr><td>Lab-02</td><td>15 L</td><td>July 2018</td></tr>
<tr><td>Lab-03</td><td>15 L</td><td>July 2018</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 remaining quantity of three trial batches.
The detail is as under:
<table>
<tr><th>Trial no.</th><th>Total no. of Bottles for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr>
<tr><td>01</td><td>91</td><td>30</td><td>61</td></tr>
<tr><td>02</td><td>91</td><td>30</td><td>61</td></tr>
<tr><td>03</td><td>91</td><td>30</td><td>61</td></tr>
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<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>
</table>

13.	Method used for analysis of API along with COA.	The firm has applied supplier's method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.
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 specification & Test method along with analytical method validation report. Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)
15.	Reports of stability studies of API from manufacturer.	The firm has submitted copies of reports of 06 Months Accelerated and Real Time Stability Study Data of 03 Batches of API M/s. SI Group, Inc.
16.	Analysis reports for excipients used.	The firm has submitted copies of its own Analytical reports for all excipients used in product development of IBURO 400mg/100ml Infusion
17.	Drug-excipients compatibility studies.	The firm has submitted Compatibility study report (dated 13-06-2018) along with raw data sheets and relevant chromatograms.
18.	Record of comparative dissolution data	Firm has submitted Comparative Dissolution Profile protocol & reports. The details of reference product & Sample product are as follows: **Feature** / **Reference Product** / **Product of M/s SAMI** Brand Name / Ibuprofen Infusion / Ibuprofen Infusion Batch No. / 18301406 / LAB-01 Exp. Date / June - 2020 / -
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for complete stability studies analysis of three batches.
Remarks of Evaluator:		
• Justify the quantity of API i.e. 402.857/vial used in the formulation as the label claim is 400mg/100ml.		The quantity of API as per label claim is 400mg/100ml whereas the calculated quantity of API is 402.857mg/100ml which is according to its potency. However, the quantity of API per 100ml will remain same as of label claim.

Decision: Registration Board decided to approve registration of "IBURO 400mg/100ml Infusion (Ibuprofen)" with Innovator's specifications by M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 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.

813.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	IBURO 600mg/100ml Infusion
	Composition	Each 100ml contains: Ibuprofen BP ……600mg
	Diary No. Date of R& I & fee	Dy N.15670;07-03-2019: 50,000/- (04-03-2019)
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5D
	Finished product Specification	Innovator's Specification
	Pack size & Demanded Price	100ml : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 600mg/100ml Infusion of MHRA approved
	Me-too status	N/A
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good

		compliance with GMP.
	Remarks of the Evaluator	Both SVP and LVP sections are present.

STABILITY STUDY DATA

Drug	IBURO 600mg/100ml Infusion		
Name of Manufacturer	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi.		
Manufacturer of API	SI Group ,Orangeburg, SC, USA		
API Lot No.	Lot#: 4050-3159 , Quantity; 5 kg		
Description of Pack (Container closure system)	Glass bottle USP Type – II		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Lab#01	Lab#02	Lab#03
Batch Size	15 L	15 L	15 L
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	July 2018	July 2018	July 2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch#4050-3159) from M/S SI Group ,Orangeburg, SC, USA 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	SI Group, Inc. ,725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA)
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 Commercial invoice No. 442831 dated 05-09-2017 attested by ADC (Karachi) dated 09-10-2017 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

REMARKS OF EVALUATORS

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION ROM 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:

Administration portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Firm has referred last onsite panel inspection for instant dosage form conducted during last two years IBURO *(Ibuprofen)* 800mg/8ml Injection on 28th January, 2019 by following panel: 1. Dr. Rafeeq Alam Khan, Meritorious Professor, Member Registration Board

<table>
<tr><td></td><td></td><td>2. Mr. Aslam Shah, Member Registration Board.
3. Mr. Affan Ali Qureshi, Assistant Director (CDL), DRAP, Karachi.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Copy of Form 6 License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 09-10-2017, for the import of Ibuprofen from M/s. SI Group, Inc., 725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA)
Copy of Commercial invoice No. 442831 dated 05-09-2017 attested by ADC (Karachi) dated 09-10-2017 has been submitted .</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted pro forma of Working /reference standard from EDQM.</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>SI Group, Inc., 725 Cannon Bridge Road, Orangeburg, South Carolina (SC) 29115, United States (USA) Registration of Establishment No. 3011012288</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Work instruction for Evaluation of Suppliers and vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has Certificate of Analysis for API, working standards and impurity standard.</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 & COAs of all the excipients used in formulation of IBURO 600mg/100ml Infusion, from relevant manufacturers</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted copy of List of qualified staff their involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for development & stability testing of trial batches.</td><td>The firm has submitted photocopy of SOP for development of IBURO 600mg/100ml Infusion Stability protocol.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Batch manufacturing Record of the following 3 batches Three stability batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Lab-01</td><td>15 L</td><td>June 2018</td></tr>
<tr><td>Lab-02</td><td>15 L</td><td>June 2018</td></tr>
<tr><td>Lab-03</td><td>15 L</td><td>June 2018</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 remaining quantity of three trial batches.
The detail is as under:
<table>
<tr><th>Trial no.</th><th>Total no. of Bottles for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr>
<tr><td>01</td><td>91</td><td>30</td><td>61</td></tr>
<tr><td>02</td><td>91</td><td>30</td><td>61</td></tr>
<tr><td>03</td><td>91</td><td>30</td><td>61</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 applied supplier’s method for analysis of API and has submitted analytical reports, raw data sheets & relevant chromatograms.</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 specification & Test method along with analytical method validation report.
Firm has submitted complete record of testing of stability</td></tr>
</table>

<table>
<tr><td></td><td></td><td>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 Real Time Stability Study Data of 03 Batches of API M/s. SI Group, Inc.</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 of IBURO 600mg/100ml Infusion</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Compatibility study report (dated 13-06-2018) along with raw data sheets and relevant chromatograms.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data</td><td>Firm has submitted Comparative analysis reports. The details of reference product & Sample product are as follows:
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of M/s SAMI</th></tr>
<tr><td>Brand Name</td><td>Ibuprofen Infusion</td><td>Ibuprofen Infusion</td></tr>
<tr><td>Batch No.</td><td>18301411</td><td>LAB-01</td></tr>
<tr><td>Exp. Date</td><td>June - 2020</td><td>-</td></tr>
</table></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 complete stability studies analysis of three batches.</td></tr>
<tr><td colspan="3">Remarks of Evaluator:</td></tr>
<tr><td colspan="2">• Justify the quantity of API i.e. 605.285/vial used in the formulation as the label claim is 600mg/100ml.</td><td>The quantity of API as per label claim is 600mg/100ml whereas the calculated quantity of API is 604.285mg/100ml which is according to its potency. However, the quantity of API per 100ml will remain same as of label claim.</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of “IBURO 600mg/100ml Infusion (Ibuprofen)” with Innovator’s specifications by M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 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>
<tr><td>814.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Deflazot Tablets 6mg</td></tr>
<tr><td></td><td>Composition</td><td>Each Compressed tablets contains:
Deflazacort .....6mg</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy. No.16554 dated : 07-03-2019 Rs.20,000/- 07-03-2019</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Corticosteroids</td></tr>
<tr><td></td><td>Type of Form</td><td>Form – 5</td></tr>
<tr><td></td><td>Finished product Specifications</td><td>Manufacturer’s Specifications</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>20's, 30's, ; As per SRO</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities</td><td>Approved in US-FDA (EMFLAZA Tablet 6mg)</td></tr>
<tr><td></td><td>Me-too status (with strength and dosage form)</td><td>CALCORT TABLETS 6mg of M/s HOECHST KARACHI (Reg No# 025224)</td></tr>
<tr><td></td><td>GMP status</td><td>GMP Inspection conducted on 09-11-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.</td></tr>
<tr><td colspan="3">STABILITY STUDY DATA</td></tr>
<tr><td colspan="2">Drug</td><td>Deflazot Tablets 6mg</td></tr>
<tr><td colspan="2">Name of Manufacturer</td><td>M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.</td></tr>
</table>

Manufacturer of API	M/s Anuh Pharma Ltd.		
API Lot No.	APL/191/1-17 (Deflazacort)		
Description of Pack (Container closure system)	Alu -Alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 9 Months		
Frequency	Real Time: 0,3,6 & 9 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	Trial# 01	Trial# 02	Trial# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	03/2018	03/2018	03/2018
Date of Initiation	03/05/2018	03/05/2018	03/05/2018
No. of Batches	03		
Date of Submission	(16629) 07-03-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. #	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India
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.6080699) issued by Food & Drugs Administration Konkan Division, Maharashtra State. It is valid until 21/03/2019.
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 No; EXP/276/2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018
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 submitted 26 Weeks Accelerated and 38 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

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was

<table>
<tr><td></td><td>two years.</td><td>presented Initially in 256th subsequently in 269th&finally in 276th meeting of Registration board.
Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed.
The firm has 21CFR compliant HPLC software.
The firm has audit trail reports available.</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 No; EXP/276/2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copies of COA for following working standard:</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 declaring following information:
Certificate No.6080699 Issued to: M/s Anuh Pharma Ltd, India. Issued by: Food & Drug Administration, Konkan Division, Maharashtra State. Validity: Valid Till 21-03-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Applicant has submitted following COAs:
Copy of COA of API (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India has been submitted.
Copy of COA of reference standard of Deflazacort (batch # APL/150/G-17) 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 all the excipients used in the formulation of applied product.
Commercial invoice dated 26-09-17 for Corn Starch.
Commercial invoice dated 10-11-17 for Lactose.
Commercial invoice dated 25-09-17 for Aerosil.
Commercial invoice dated 03-11-16 for Magnesium Stearate</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 evelopment & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Deflazot Tablets 6mg</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 of the 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>Mar-18</td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>Mar-18</td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>Mar-18</td></tr>
</table></td></tr>
</table>

11.	Record of remaining quantities of stability batches.	The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches. The detail is as under:

Trial no.	Total no. of tablets for stability	Used quantities	Remaining quantities
Trial # 01	1190 Tab (60 packs * 20's)	320 Tab (16 packs * 20's)	880 Tab (44 packs * 20's)
Trial # 02	1170 Tab (58 packs * 20's)	300 Tab (15 packs * 20's)	860 Tab (43 packs *20's)
Trial # 03	1160 Tab (58 packs * 20's)	300 Tab (15 packs * 20's)	860 Tab (43 packs *20's)

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 chambers used in Real Time & Accelerated stability studies of applied product from 01-05-2018 to 13-02- 2019.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: Raw Material Test/Analysis Procedures & Raw Material Specifications Of Deflazacort (in house) .
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 photocopies of following: FPP Test/Analysis Method & FPP Specifications (In-house) for Deflazot Tablets 6mg.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Deflazacort from M/s Anuh Pharma Ltd, India according to zone IVA conditions.
16.	Analysis reports for excipients used.	The firm has submitted copy 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.	Exemption Claimed as the reference product is not available in Pakistan.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of Deflazacort from 28-03-2018 to 7-02-2019 was submitted by the firm.

Remarks of Evaluator:

- Record of comparative dissolution datanot provided according to firmExemption Claimed as the reference product is not available in Pakistan.

Sr. #	Deficiencies/Shortcomings	Reply by Firm
1.	In T# 01final mixing of powder was done on (12-03-2018) and compression was done on 25-04-2018 .Justify.	In Trial # 01 final mixing of granules was done on 12-03-2018, and in process analysis carried out on 28-03-2018, then trial was compressed into two steps. Initially small amount of granules were compressed on 31-03-2018. After its analysis on 23-04-2018 (compressed tablets) the remaining granules were compressed on 25-04-2018. Granules were stored/kept in sealed bag and well closed container during the process Evidence weight variation sheet (attached)
2.	In all 3 batches approval for blistering was 23-04-2018 while compression done on 25- 04-2018. Justify.	The Initial compression of the batches was done on 31-03-2018 after which the compressed tablet were analysed on 23-04-2018 and approval for the blistering for initially compressed tablets was given. However, the remaining granules were compressed

		on 23-04-2018 and the process of blistering was carried out on 30-04-2018. In this way the trial got compressed in two steps. The whole trial was not initially compressed due to limited quantity of API and once the initially compressed tablets were passed the remaining trial got compressed.
3.	In all 3 batches compression was done on 25-04-2018 while some analytical test were performed on 31-03-2018 as per submitted batch manufacturing record. Justify	As the compression of tablets done in two steps, the analytical tests like D.Time, Friability etc., for initially compressed tablet was carried out on 31-03-2018 on the date of initial compression and remaining granules were compressed on 25-04-2018 as evident from weight variation sheet.
4.	In T# 02 & T# 03 final mixing of powder was done on (23-03-2018) and compression done on 25-04-2018 .Justify	In T# 02 and T# 03 final mixing of granules was done on 28-03-2018. Initially some granules were compressed on 31-03-2018 and once passed through analysis on23-04-2018 the remaining trial got compressed on 25-04-2018as evident from weight variation sheet.
5.	In T# 01, 3rd month for Real time stability assay chromatograms not matching raw data sheets. Justify	Typographical error in raw data sheet. Corrected raw data sheets attached.
6.	In Batch No T # 02, 6th month for Real time stability dissolution chromatograms not matching raw data sheets. Justify.	Typographical error in raw data sheet. Corrected raw data sheets attached.

Decision: Registration Board deferred for onsite verification of stability studies.

815.	Name and address of manufacturer / Applicant	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Deflazot Tablets 18mg
	Composition	Each Compressed tablets contains: Deflazacort 18mg
	Diary No. Date of R& I & fee	Dy. No.16555 dated : 07-03-2019 Rs.50000/- 07-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form – 5 D
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA (EMFLAZA Tablet 18mg)
	Me-too status (with strength and dosage form)	Nil
	GMP status	GMP Inspection conducted on 09-11-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Deflazot Tablets 18mg
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
Manufacturer of API	M/s Anuh Pharma Ltd.
API Lot No.	APL/191/1-17 (Deflazacort)
Description of Pack (Container closure system)	Alu -Alu Blister Pack in Unit carton
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 9 Months
Frequency	Real Time: 0,3,6 & 9 (months) Accelerated: 0,1,2,3,4 & 6 (months)

Batch No.	Trial# 01	Trial# 02	Trial# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	03/2018	03/2018	03/2018
Date of Initiation	04/05/2018	04/05/2018	04/05/2018
No. of Batches	03		
Date of Submission	(16630) 07-03-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India
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.6080699) issued by Food & Drugs Administration Konkan Division, Maharashtra State. It is valid until 21/03/2019.
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 No.EXP/ 276 /2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018
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 submitted 26 Weeks Accelerated and 38 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

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th&finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice No; EXP/276/2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018.
3.	Documents for the procurement of reference standard and impurity	The firm has submitted copies of COA for following working standard :

<table>
<tr><td></td><td>standards.</td><td></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 declaring following information:
Certificate No.6080699 Issued to: M/s Anuh Pharma Ltd, India. Issued by: Food & Drug Administration, Konkan Division, Maharashtra State.
Validity: Valid Till 21-03-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td>Applicant has submitted following COAs:
• Copy of COA of API (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India has been submitted.
• Copy of COA of reference standard of Deflazacort (batch # APL/150/G-17) 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 all the excipients used in the formulation of applied product.
• Commercial invoice dated 26-09-17 for Corn Starch.
• Commercial invoice dated 10-11-17 for Lactose.
• Commercial invoice dated 25-09-17 for Aerosil.
• Commercial invoice dated 03-11-16 for Magnesium Stearate</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 Deflazot Tablets 6mg</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 of the 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>Mar-18</td></tr><tr><td>Trial # 02</td><td>1500 tablets</td><td>Mar-18</td></tr><tr><td>Trial # 03</td><td>1500 tablets</td><td>Mar-18</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 remaining quantity of three trial batches.
The detail is as under:
<table><tr><th>Trial no.</th><th>Total no. of tablets for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr><tr><td>Trial # 01</td><td>1180 Tab (59 packs * 20’s)</td><td>320 Tab (16 packs * 20’s)</td><td>860 Tab (43 packs * 20’s)</td></tr><tr><td>Trial # 02</td><td>1160 Tab (58 packs * 20’s)</td><td>300 Tab (15 packs * 20’s)</td><td>860 Tab (43 packs * 20’s)</td></tr><tr><td>Trial # 03</td><td>1211 Tab (60 packs * 20’s)</td><td>300 Tab (15 packs * 20’s)</td><td>900 Tab (45 packs * 20’s)</td></tr></table></td></tr>
</table>

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 chambers used in Real Time & Accelerated stability studies of applied product from 01-05-2018 to 13-02- 2019.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: Raw Material Test/Analysis Procedures & Raw Material Specifications Of Deflazacort (in house) .
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 photocopies of following: FPP Test/Analysis Method & FPP Specifications (In-house) for Deflazot Tablets 18mg.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Deflazacort from M/s Anuh Pharma Ltd, India according to zone IVA conditions.
16.	Analysis reports for excipients used.	The firm has submitted copy 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.	Exemption Claimed as the reference product is not available in Pakistan.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of Deflazacort from 28-03-2018 to 7-02-2019 was submitted by the firm.

Remarks of Evaluator:

- Record of comparative dissolution datanot provided according to firmExemption Claimed as the reference product is not available in Pakistan.

Sr.#	Deficiencies/Shortcomings	Reply by Firm
1.	In all 3 batches final mixing of powder was done on (31-03-2018) and compression done on 25-04-2018 .Justify..	In all three batches final mixing of granules was done on 31-03-2018, and in process analysis carried out on 03-04-2018, then trial was compressed into two steps. Initially small amount of granules were compressed on 21-04-2018. After its analysis on 23-04-2018 (compressed tablets) the remaining granules were compressed on 25-04-2018. Granules were stored/kept in sealed bag and well closed container during the process Evidence weight variation sheet (attached)
2.	In all 3 batches compression was done on 25-04-2018 while some analytical test were performed on 21-04-2018 as per submitted batch manufacturing record. Justify	As the compression of tablets done in two steps, the analytical tests like D.Time, Friability etc., for initially compressed tablet was carried out on 21-04-2018 on the date of initial compression and remaining granules were compressed on 25-04-2018 as evident from weight variation sheet
3.	In all 3 batches approval for blistering was 24-04-2018 while compression done on 25-04-2018. Justify	The Initial compression of the batches was done on 21-04-2018 after which the compressed tablet were analysed on 24-04-2018 and approval for the blistering for initially compressed tablets was given. However, the remaining granules were compressed on 25-04-2018 and the process of blistering was carried out on 30-04-2018. In this way the trial got compressed in two steps. The whole trial was not initially compressed due to limited quantity of API and once the initially compressed tablets were passed the remaining trial got compressed.

Decision: Registration Board deferred for onsite verification of stability studies.

816.	Name and address of manufacturer / Applicant	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Deflazot Tablets 30mg
	Composition	Each Compressed tablets contains: Deflazacort 30mg

	Diary No. Date of R& I & fee	Dy. No.16556 dated : 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form – 5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA (EMFLAZA Tablet 30mg)
	Me-too status (with strength and dosage form)	CALCORT TABLETS 6mg of M/s HOECHST KARACHI (Reg No# 025224)
	GMP status	GMP Inspection conducted on 09-11-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Deflazot Tablets 30mg		
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	M/s Anuh Pharma Ltd.		
API Lot No.	APL/191/1-17 (Deflazacort)		
Description of Pack (Container closure system)	Alu -Alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 9 Months		
Frequency	Real Time: 0,3,6 & 9 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	Trial# 01	Trial# 02	Trial# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04/2018	04/2018	04/2018
Date of Initiation	07/05/2018	07/05/2018	07/05/2018
No. of Batches	03		
Date of Submission	(16631) 07-03-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India
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.6080699) issued by Food & Drugs Administration Konkan Division, Maharashtra State. It is valid until 21/03/2019.
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 No; EXP/276/2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018

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 submitted 26 Weeks Accelerated and 38 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

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th&finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice No; EXP/276/2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard :
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 declaring following information: Certificate No.6080699 Issued to: M/s Anuh Pharma Ltd, India. Issued by: Food & Drug Administration, Konkan Division, Maharashtra State. Validity: Valid Till 21-03-2019.
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	Applicant has submitted following COAs: • Copy of COA of API (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India has been submitted. • Copy of COA of reference standard of Deflazacort (batch # APL/150/G-17) 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. • Commercial invoice dated 26-09-17 for Corn Starch. • Commercial invoice dated 10-11-17 for Lactose. • Commercial invoice dated 25-09-17 for Aerosil. • Commercial invoice dated 03-11-16 for Magnesium Stearate
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.

<table>
<tr><th colspan="3">Production Data</th></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the Development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Deflazot Tablets 30mg</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 of the 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>Apr-18</td></tr><tr><td>Trial # 02</td><td>1500 tablets</td><td>Apr-18</td></tr><tr><td>Trial # 03</td><td>1500 tablets</td><td>Apr-18</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 remaining quantity of three trial batches.
The detail is as under:

<table><tr><th>Trial no.</th><th>Total no. of tablets for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr><tr><td>Trial # 01</td><td>1030 Tab (52 packs * 20’s)</td><td>320 Tab (16 packs * 20’s)</td><td>560 Tab (38 packs * 20’s)</td></tr><tr><td>Trial # 02</td><td>1060 Tab (53 packs * 20’s)</td><td>300 Tab (15 packs * 20’s)</td><td>760 Tab (38 packs * 20’s)</td></tr><tr><td>Trial # 03</td><td>1040 Tab (52 packs * 20’s)</td><td>300 Tab (15 packs * 20’s)</td><td>740 Tab (37 packs * 20’s)</td></tr></table></td></tr>
<tr><th colspan="3">QA / QC DATA</th></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-05-2018 to 13-02- 2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopies of following:
Raw Material Test/Analysis Procedures & Raw Material Specifications Of Deflazacort (in house) .</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 photocopies of following:
FPP Test/Analysis Method & FPP Specifications (In-house) for Deflazot Tablets 30mg.</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 36 Months Real Time Stability Study Data of 03 Batches of Deflazacort from M/s Anuh Pharma Ltd, India according to zone IVA conditions.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has used the excipients of innovator.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Exemption Claimed as the reference product is not available in Pakistan.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Audit trail on testing reports of Deflazacort from 28-03-2018 to 7-02-2019 was submitted by the firm.</td></tr>
<tr><th colspan="3">Remarks of Evaluator:</th></tr>
<tr><td colspan="3">Record of comparative dissolution datanot provided according to firmExemption Claimed as the reference product is not available in Pakistan.</td></tr>
</table>

Sr.#	Deficiencies/Shortcomings	Reply by Firm
1.	In all 3 batches final mixing of powder was done on (12-04-2018) and compression was done on (27-04-2018) .Justify.	In all three batches final mixing of granules was done on 12-04-2018, and in process analysis carried out on 25-04-2018, then trial was compressed into two steps. Initially small amount of granules were compressed on 25-04-2018. After the analysis compressed tablets the remaining granules were compressed on 27-04-2018. Granules were stored/kept in sealed bag and well closed container during the process Evidence weight variation sheet (attached)
2.	In all 3 batches approval for blistering was 26-04-2018 while compession done on 27-04-2018. Justify	The Initial compression of the batches was done on 25-04-2018 after which the compressed tablet were analysed on 26-04-2018 and approval for the blistering for initially compressed tablets was given. However, the remaining granules were compressed on 27-04-2018 and the process of blistering was carried out on 02-05-2018. In this way the trial got compressed in two steps. The whole trial was not initially compressed due to limited quantity of API and once the initially compressed tablets were passed the remaining trial got compressed.
3.	In all 3 batches compression done on 27-04-2018 while some analytical test were performed on 25-04-2018 as per submitted batch manufacturing record. Justify	As the compression of tablets done in two steps, the analytical tests like D.Time, Friability etc., for initially compressed tablet was carried out on 25-04-2018 on the date of initial compression and remaining granules were compressed on 27-04-2018 as evident from weight variation sheet.

Decision: Registration Board deferred for onsite verification of stability studies.

817.	Name and address of manufacturer / Applicant	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Deflazot Tablets 36mg
	Composition	Each Compressed tablets contains: Deflazacort 36mg
	Diary No. Date of R& I & fee	Dy. No.16557 dated : 07-03-2019 Rs.50,000/- 07-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form – 5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA (EMFLAZA Tablet 36mg)
	Me-too status (with strength and dosage form)	Not avaiable
	GMP status	GMP Inspection conducted on 09-11-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Deflazot Tablets 36mg
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
Manufacturer of API	M/s Anuh Pharma Ltd.
API Lot No.	APL/191/1-17 (Deflazacort)
Description of Pack (Container closure system)	Alu -Alu Blister Pack in Unit carton

Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 9 Months		
Frequency	Real Time: 0,3,6 & 9 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	Trial# 01	Trial# 02	Trial# 03
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	04/2018	04/2018	04/2018
Date of Initiation	08/05/2018	08/05/2018	08/05/2018
No. of Batches	03		
Date of Submission	(16632) 07-03-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India
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.6080699) issued by Food & Drugs Administration Konkan Division, Maharashtra State. It is valid until 21/03/2019.
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 No.EXP/ 276 /2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018
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 submitted 26 Weeks Accelerated and 38 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

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th &finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed.

<table>
<tr><td></td><td></td><td>• The firm has 21CFR compliant HPLC software.
• The firm has audit trail reports available.</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 No; EXP/276/2018 dated 20-12-2017 (Deflazacort) attested by ADC, DRAP, Islamabad dated; 18-01-2018.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copies of COA for following working standard:</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 declaring following information:
Certificate No.6080699Issued to: M/s Anuh Pharma Ltd, India.
Issued by: Food & Drug Administration, Konkan Division, Maharashtra State. Validity: Valid Till 21-03-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Applicant has submitted following COAs:
• Copy of COA of API (batch # APL/191/1-17) from M/s Anuh Pharma Ltd. India has been submitted.
• Copy of COA of reference standard of Deflazacort (batch # APL/150/G-17) 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 all the excipients used in the formulation of applied product.
• Commercial invoice dated 26-09-17 for Corn Starch.
• Commercial invoice dated 10-11-17 for Lactose.
• Commercial invoice dated 25-09-17 for Aerosil.
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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 Deflazot Tablets 36mg</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 of the 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>Apr-18</td></tr><tr><td>Trial # 02</td><td>1500 tablets</td><td>Apr-18</td></tr><tr><td>Trial # 03</td><td>1500 tablets</td><td>Apr-18</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 remaining quantity of three trial batches.
The detail is as under:
<table><tr><th>Trial no.</th><th>Total no. of tablets for stability</th><th>Used quantities</th><th>Remaining quantities</th></tr><tr><td>Trial # 01</td><td>1280 Tab (64 packs * 20’s)</td><td>320 Tab (16 packs * 20’s)</td><td>960 Tab (48 packs * 20’s)</td></tr></table></td></tr>
</table>

		Trial # 02	1260 Tab (63 packs * 20's)	300 Tab (15 packs * 20's)	960 Tab (48 packs * 20's)
		Trial # 03	1320 Tab (66 packs * 20's)	300 Tab (15 packs * 20's)	1020 Tab (51 packs * 20's)
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 chambers used in Real Time & Accelerated stability studies of applied product from 01-05-2018 to 13-02- 2019.			
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: Raw Material Test/Analysis Procedures & Raw Material Specifications Of Deflazacort (in house) .			
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 photocopies of following: FPP Test/Analysis Method & FPP Specifications (In-house) for Deflazot Tablets 36mg.			
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Deflazacort from M/s Anuh Pharma Ltd, India according to zone IVA conditions.			
16.	Analysis reports for excipients used.	The firm has submitted copy 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.	Exemption Claimed as the reference product is not available in Pakistan.			
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of Deflazacort from 28-03-2018 to 7-02-2019 was submitted by the firm.			

Remarks of Evaluator:

- Record of comparative dissolution datanot provided according to firmExemption Claimed as the reference product is not available in Pakistan.

Sr. No.	Deficiencies/Shortcomings	Reply by Firm
1.	In all 3 batches final mixing of powder was done on (17-04-2018) and compression done on (30-04-2018) . Justify	In all three batches final mixing of granules was done on 18-04-2018, and in process analysis carried out on 25-04-2018, then trial was compressed into two steps. Initially small amount of granules were compressed on 26-04-2018. After its analysis on 27-04-2018 (compressed tablets) the remaining granules were compressed on 30-04-2018. Granules were stored/kept in sealed bag and well closed container during the process Evidence weight variation sheet (attached)
2.	In batch No. T# 01 & T# 02 approval for blistering was 27-04-2018 while compression done on 30-04-2018. Justify.	The Initial compression of the Trial #01 & 02 was done on 26-04-2018 after which the compressed tablet were analysed on 27-04-2018 and approval for the blistering for initially compressed tablets was given. However, the remaining granules were compressed on 30-04-2018 and the process of blistering was carried out on 02-05-2018. In this way the trial got compressed in two steps. The whole trial was not initially compressed due to limited quantity of API and once the initially compressed tablets were passed the remaining trial got compressed.
3.	In batch No. T#03 approval for blistering was 28-04-2018 while compassion done on 30-04-2018	The Initial compression of the Trial #03 was done on 26-04-2018 after which the compressed tablet were analysed on 28-04-2018 and approval for the blistering for

		initially compressed tablets was given. However, the remaining granules were compressed on 30-04-2018 and the process of blistering was carried out on 02-05-2018. In this way the trial got compressed in two steps. The whole trial was not initially compressed due to limited quantity of API and once the initially compressed tablets were passed the remaining trial got compressed.
4.	In all 3 batches compression on 30-04-2018 while some analytical test were performed on 26-04-2018 as per submitted batch manufacturing record. Justify	As the compression of tablets done in two steps, the analytical tests like D.Time, Friability etc., for initially compressed tablet was carried out on 26-04-2018 on the date of initial compression and remaining granules were compressed on 30-04-2018 as evident from weight variation sheet.
Decision: Registration Board deferred for onsite verification of stability studies.		

Evaluator PEC-V

Case no. 01 Registration Applications for Local Manufacturing of (Human) Drugs.

a. New Cases

818.	Name and address of manufacturer / Applicant	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, S.I.T.E. Super Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Mismol 500mg Tablet
	Composition	Each tablet contains: Paracetamol…500mg
	Diary No. Date of R& I & fee	Dy. No. 6826, 22-02-2018, Rs. 20,000/- (22-02-2018)
	Pharmacological Group	Analgesics
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	200's for Rs. 180/-, Jar of 1x1000's: Rs, 665/-
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Feveren Tablet 500mg of M/s Asian Continental Karachi (Reg. # 076689)
	GMP status	Last GMP inspection was conducted on 24-09-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator	• General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved.	
819.	Name and address of manufacturer / Applicant	M/s Mission Pharmaceuticals Pvt Ltd. Plot No. A-94, S.I.T.E. Super Highway Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Merzole 40mg capsule
	Composition	Each capsule contains: Esomeprazole Magnesium (enteric-coated pellets)……..40mg
	Diary No. Date of R & I & fee	Dy. No. 6828,22-02-2018, Rs. 20,000/- (22-02-2018)
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	7'sx2 &Rs. 323.00/-
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Esoact 40mg capsule of M/s UmemaPharmaBalochistan (Reg. # 076535)
	GMP status	Last GMP inspection was conducted on 24-09-2018 and the report concludes good level of GMP compliance.

	Remarks of the Evaluator.	• General capsule section is available in the firm as mentioned in the submitted section approval letter. Source of pellets is M/s Vision Pharma. • CoA of manufacturer, stability data of pellets and GMP certificate of manufacturer is submitted by the firm which was valid until **25-01-2019.**
	Decision: Approved.	
820.	Name and address of manufacturer / Applicant	M/s WelbornePharmachem and Biologicals, Plot no. 51/1, 52/2, Phase I and II Industrial Estate , Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Nebron Tablet 2.5mg
	Composition	Each film coated tablet contains: Nebivolol as HCl……..2.5mg
	Diary No. Date of R& I & fee	Diary No:3056, 23/01/2018, Rs: 20,000/- Dated 22/01/2018
	Pharmacological Group	Beta blocking agents, selective (C07AB12)
	Type of Form	Form 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	2x7's , AluAlu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic USFDA Approved
	Me-too status	061344; Nebil 2.5mg Tablet M/s Getz Karachi
	GMP status	Last GMP inspection was conducted on 27-06-2018 and thereport concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is available as uncoated in MHRA and USFDA while the firm has applied as film-coated tablet. • No USP or BP monograph is available for the applied formulation.
	Decision: Deferred for revision of formulation to uncoated tablet as per reference product along with submission of fee for revision of formulation.	
821.	Name and address of manufacturer / Applicant	M/s WelbornePharmachem and Biologicals, Plot no. 51/1, 52/2, Phase I and II Industrial Estate , Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Nebron Tablet 5mg
	Composition	Each film coated tablet contains: Nebivolol as HCl……5mg
	Diary No. Date of R& I & fee	Diary No:3057, 23/01/2018, Rs: 20,000/- Dated 22/01/2018
	Pharmacological Group	Beta blocking agents, selective (C07AB12)
	Type of Form	Form 5
	Finished product Specification	**Not claimed**
	Pack size & Demanded Price	2x7's , AluAlu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic USFDA Approved
	Me-too status	061345 Nebil 5mg Tablet M/s Getz Karachi
	GMP status	Last GMP inspection was conducted on 27-06-2018 and thereport concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is available as uncoated in MHRA and USFDA while the firm has applied as film-coated tablet. • No USP or BP monograph is available for the applied formulation.
	Decision: Deferred for revision of formulation to uncoated tablet as per reference product along with submission of fee for revision of formulation.	

822.	Name and address of manufacturer / Applicant	M/s WelbornePharmachem and Biologicals, Plot no. 51/1, 52/2, Phase I and II Industrial Estate , Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Nebron Tablet 10mg
	Composition	Each film coated tablet contains: Nebivolol as HCl……..10mg
	Diary No. Date of R& I & fee	Diary No:3058, 23/01/2018, Rs: 20,000/- Dated 22/01/2018
	Pharmacological Group	Beta blocking agents, selective (C07AB12)
	Type of Form	Form 5
	Finished product Specification	**Not claimed**
	Pack size & Demanded Price	2x7's , AluAlu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities	Bystolic USFDA Approved
	Me-too status	061345 Nebil 5mg Tablet M/s Getz Karachi
	GMP status	Last GMP inspection was conducted on 27-06-2018 and thereport concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is available as uncoated in MHRA and USFDA while the firm has applied as film-coated tablet. • No USP or BP monograph is available for the applied formulation.
	Decision: Deferred for revision of formulation to uncoated tablet as per reference product along with submission of fee for revision of formulation.	

B. DEFERRED CASES

823.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A Sundar Industrial Estate, Raiwind Road ,Lahore
	Brand Name +Dosage Form + Strength	Diafax Tablet 550mg
	Composition	Each film coated tablet contains: Rifaximin…….550mg
	Diary No. Date of R& I & fee	Diary No:3061, 23/01/2018, Rs: 20,000/- 18/01/2018
	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® USFDA Approved
	Me-too status	081073; Rixago 550mg 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.
	Previous remarks of the Evaluator	Tablet Section is approved.
	Previous decision	Deferred in 288th 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 submitted its latest GMP inspection report dated: 29-03-2019 concluding satisfactory level of GMP compliance. • Firm has General Tablet section as mentioned in the submitted GMP inspection report.
	Decision:Approved with innovator's specification.	

824.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd, 539-A Sundar Industrial Estate, Raiwind Road,Lahore
	Brand Name +Dosage Form + Strength	Diafax Tablet 200mg
	Composition	Each film coated tablet contains: Rifaximin…….200mg
	Diary No. Date of R& I & fee	Diary No:3060, 23/01/2018, Rs: 20,000/- 18/01/2018
	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® USFDA Approved
	Me-too status	081073; Rixago 550mg M/s OBS Pharma Karachi.
	GMP status	As recorded for above application
	Previous remarks of the Evaluator	Tablet Section is approved.
	Previous decision	Deferred in 288th 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 submitted its latest GMP inspection report dated: 29-03-2019 concluding satisfactory level of GMP compliance. • Firm has General Tablet section as mentioned in the submitted GMP inspection report.
	Decision:Approved with innovator's specification.	
825.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals, Plot No. 208C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Itomed tablet 50mg
	Composition	Each film coated tablet contains: Itopride as hydrochloride….50mg
	Diary No. Date of R& I & fee	Dy.No.1364; 23-07-2018; Rs.20,000/- (26-06-2018)
	Pharmacological Group	Gastroprokinetic / Propulsives
	Type of Form	Form- 5
	Finished product Specification	Innovator specifications
	Pack size & Demanded Price	10's, 30's AluAlu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved In PMDA
	Me-too status	Ganaton 50mg Tablet by M/s Abbott. (Reg. # 028429)
	GMP status	Grant of New DML Approved dated 13-06-2018
	Previous remarks of the Evaluator	The formulation is approved in reference regulatory authority as Itopride hydrochloride whereas, firm has applied for Itopride (as hydrochloride). Firm has revised their formulation.
	Previous decision	Deferred in 284th DRB meeting for submission of fee for revision of formulation from "Itopride as hydrochloride" to "Itopride hydrochloride".--
	Evaluation by PEC	• Firm has revised its formulation with the label claim: Each film coated tablet contains: Itopride Hydrochloride….50mg • Rs. 5000/- fees is submitted by the firm.
	Decision:Approved with innovator's specification with revised label claim as follows: **Each film coated tablet contains:** **Itopride Hydrochloride….50mg**	

Case no. 02 Registration Applications of Categories to be Considered on Priority.

b. Local Manufacturing Applications of Priority Categories Defined by Registration Board in its 257th Meeting

826.	Name and address of manufacturer / Applicant	M/s Biomark Pharmaceuticals Plot 527, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Folic Tablet 5 mg
	Composition	Each uncoated tablet contains: Folic Acid ……..……5mg
	Diary No. Date of R& I & fee	Dy.No;16429 Date:03-05-18 , Rs.20,000/-
	Pharmacological Group	Vitamin B9
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's AluAlu Blister As per SRO (10% less then Brand Leader)
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Folimic tablets 5mg of M/s Alliance Pharmaceuticals
	GMP status	Last inspection conducted on 10-03-2017 for Grant of DML.Panel recommends grant of DML.
	Previous remarks of the Evaluator	
	Previous decision	In 284st DRB meeting, Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	• Firm has submitted its GMP certificate based on evaluation conducted on 16-08-2018.
	Decision: Approved.	

Evaluator PEC-VI

Case no. 01: Registration Applications for Local Manufacturing of (Human) Drugs.

a. New Cases		
827.	Name and address of manufacturer / Applicant	M/s Caliph Pharmaceuticals Plot No. 17 Risalpur, KPK
	Brand Name +Dosage Form + Strength	Listate 120mg Capsule
	Composition	Each capsule contains: Orlistat……....120mg
	Diary No. Date of R& I & fee	Dy.No. 25; 27-12-2017; Rs.20,000/- (27-12-2017) (Duplicate)
	Pharmacological Group	Lipase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per SRo, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xenical, orlistat120mg, capsule;oral, USFDA Approved.
	Me-too status	Trimzak 120mg Capsule BY SchazooZaka (Pvt) Ltd, Lahore. (Reg.# 071105)
	GMP status	Firm was granted certificate of cGMP based on evaluation conducted on 6-11-2018.
	Remarks of Evaluator	Fee challan Photocopy attached. Pellets details are not provided.
	Decision:Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	

B. DEFERRED CASES

828.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals. Plot No.249/A, Industrial, Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Medarone 200mg tablet
	Composition	Each film coated tablet contains: AmiodaroneHCl……200mg
	Diary No. Date of R& I & fee	Dy.No 1166 dated 30-10-2017 Rs. 20,000/- 25-10-2017
	Pharmacological Group	Antiarrythmatic
	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.	USFDA Approved as uncoated tablet
	Me-too status	Amid Tablets 20mg by CCL 045972
	GMP status	23-11-2017 firm was considered to be operating at fair compliancewith GMP guidelines.
	Remarks of the Evaluator.	Me-too status could not be confirmed in the available database.
	Previous Decision:	**Decision of 287th** Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.
	Evaluation by PEC:	Firm has deposited Rs. 5,000/- Deposit Slip No. (1921545) and requested (on covering letter) to change our product from film coated tablet to uncoated tablet. The firm has not submitted revised master formulation.
	Decision: Deferred for submission of documents and master formulation for uncoated tablet.	
829.	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: 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.
	Previous Decision:	**Decision of 281st 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. **Decision of 288th meeting:** Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5D alongwith stability data and differential fee.

	Evaluation by PEC:	The firm has stated the Afinitor 3mg Dispersible tablet (Everolimus…….3mg) has been approved in M.263 having .(Reg. No. 088396)
	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 differential fee.	
830.	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: 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:** Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Decision of 288th meeting:** Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm, or else application on form-5D alongwith stability data and differential fee.
	Evaluation by PEC:	The firm has stated the Afinitor 2mg Dispersible tablet (Everolimus…….3mg) has been approved in M.262.(Reg. NO. 088397)
	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 differential fee.	
831.	Name and address of manufacturer / Applicant	M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Exestane 25mg Tablets
	Composition	Each film-coated tablet contains: Exemestane…25mg
	Diary No. Date of R& I & fee	Diary No:10938, 26/03/2018, Rs. 20,000/-
	Pharmacological Group	Aromatase inhibitors (Steroidal)
	Type of Form	Form-5
	Finished product Specification	Innovator’s Specification
	Pack size & Demanded Price	3x5’s/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aromasin 25 mg coated tablets by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Ph&TExemestane 25mg Coated Tablets by M/s Mehran International (Reg#078122)
	GMP status	07-11-2017. Panel recommends grant of Additional sections
	Remarks of the Evaluator.	
	Previous Decision:	**Decision of 281st meeting:** 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. . **Decision of 286th meeting:** Deferred for clarification whether the applied product is hormone or otherwise.
	Evaluation by PEC:	The firm has stated that this product is Steroidal aromatase Inhibitor and will be manufactured in Steroidal hormone Section.
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	

Case No. 02: Registration Applications of Newly Granted DML or New Section (Veterinary)

a. Deferred Cases

832.	Name and address of manufacturer / Applicant	M/s IntervacPvt Ltd, 18-km, Lahore Sheikhupura Road, Sheikhupura
	Brand Name +Dosage Form + Strength	PBS-250 Injection
	Composition	Each vial contains: Procaine Penicillin…….15 ,00,000IU Benzyl Penicillin……..5,00,000IU Streptomycin Sulphate…..2.5gm
	Diary No. Date of R& I & fee	Dy. No 560.; 22-12-2015; Rs.20,000/- (22-12-2015)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	2.5gm sterile powder vial, Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Penivet 2.5 Injection of Star Laboratories
	GMP status	CLB in its 264th meeting held on 9th July 2018 approved 2additional sections of the firm. A) Liquid Injectable (Pencillin Veterinary Section) B) Dry Powder Injection (Penicillin Veterinary Section)
	Remarks of the Evaluator.	Me-too status could not be confirmed in the available database.
	Previous Decision:	**Decision of 287th** 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: Penivet 2.5gm Injection Reg No. 008031. It has been confirmed.
	Decision: Approved with innovator's specifications.	
833.	Name and address of manufacturer / Applicant	M/s IntervacPvt Ltd, 18-km, Lahore Sheikhupura road, Sheikhupura
	Brand Name +Dosage Form + Strength	Penfas-S Injection
	Composition	Each vial contains: Procaine Penicillin…….15,00,000IU Benzyl Penicillin……..5,00,000IU Streptomycin Sulphate…….5gm
	Diary No. Date of R& I & fee	Dy. No 568.; 22-12-2015; Rs.20,000/- (22-12-2015) (Duplicate)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	5gm sterile powder vial, Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Penivet 5 Injetion
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Fee challan photocopy attached. Me-too status could not be confirmed in the available database.
	Previous Decision:	**Decision of 287th** 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.
	Evaluation by PEC:	Firm has provided me-too as: Penivet 5gm Injection Reg No. 008032. It has been confirmed.
	Decision: Approved with innovator's specifications.	
834.	Name and address of manufacturer / Applicant	M/s IntervacPvt Ltd, 18-km, Lahore Sheikhupura road, Sheikhupura
	Brand Name +Dosage Form + Strength	PPS-360 Injectable Suspension
	Composition	Each ml contains: Procaine Penicillin……200mg Streptomycin Sulphate….160mg
	Diary No. Date of R& I & fee	Dy. No.554; 22-12-2015; Rs.20,000/- (22-12-2015)
	Pharmacological Group	Penicillin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	50ml, Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Neo-Strepen of NawanReg # 053997
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Me-too status could not be confirmed.
	Previous Decision:	**Decision of 286th** 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.
	Evaluation by PEC:	Firm has provided me-too as: Neo Strepen of Nawan laboratories Reg No. 053997
	Decision: Approved with innovator's specifications.	

Case No. 03: Registration Applications of Import Cases:

A. DEFERRED CASES

I. HUMAN

835.	Name and address of Applicant	M/s Aster Life Sciences, 32-Babar Block, New Garden Town, Lahore.
	Detail of Drug Sale License	Adress: M/s Aster Life Sciences, 32-Babar Block, New Garden Town, Lahore. Validity: 29-11-2019 Status: License to sell drugs as a Distributor.
	Name and address of manufacturer	M/s Panacea Biotec ltd, Village Malpur, Baddi, District Solan-173205, Himachal Pradesh, India.
	Name and address of marketing authorization holder	M/s Panacea Biotec ltd, Village Malpur, Baddi, District Solan-173205, Himachal Pradesh, India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 13998: 13-4-2018
	Fee including differential fee	PKR 100,000/-: 13-04-2018
	Brand Name +Dosage Form + Strength	PanimunBioral 25mg capsule(Soft gelatin)
	Composition	Each capsule contains: Cyclosporin…..25mg
	Finished Product Specification	USP
	Pharmacological Group	Calcineurin Inhibitors, ATC Code: L04AD01
	Shelf life	2Years
	Demanded Price	Rs. 1500/ 30 Capsules Rs. 2500/ 50 Capsules
	Pack size	6x5's blister strips
	International availability	USFDA Approved
	Me-too status	Gengraf Capsules by Abbott
	Detail of certificates attached	• Original Legalized COPP (No. of certificate MB/05/203/WHO/GMP/18-198) issued from Licensing Authority cum Controlling Authority Baddi-173205, Dis.Solan, Himachal Pradesh. And is valid upto 11-02-2020. The product is actually available on the market for use in the exporting country. • Photocopy of legalized Certificate of GMP issued from Health and Family Welfare Department, Himachal Pradesh, Solan (State Drugs Controller). It is valid upto 25-11-2017. Certificate No. HFW-II|Drugs|302/05 (Vol-II) • Letter of authorization issued on 26-09-2017 and is valid upto 30-April 2020, from M/s Panacea Biotec, India have submitted
	Remarks of the Evaluator. • Firm has submitted 6 months accelerated stability study(40+-2 'C, 75RH+-5%) data and 12 months real-time (30+-2 'C, 70RH+-5%) stability study data , 24 months stability data at (25'C+-2'C, 60RH+-5%RH) of 5 batches. Initiation dates: Batch #108/094A (8-10-2005) Batch #0243/010 (8-10-2005) Batch #108/094B (8-10-2005) Batch #0243/018 (8-10-2005) Batch #0243/014 (8-10-2005)	
	Decision of 287th: Deferred for justification of claimed shelf life of 2 years, since firm has submitted long term stability (30+-2 °C, 70RH±5%) data of 12 months only. Confirmation from Import Policy order regarding import of applied formulationfrom India. **Evaluation of PEC:** The firm has submitted long term stability data of 36 months of 3 batches and	

	requested to consider our shelf-life as 36 months. Regarding confirmation of Import policy the firm submitted that formulation is not included in the list of restricted items.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	
836.	Name and address of Applicant	M/s Aster Life Sciences, 32-Babar Block, New Garden Town, Lahore.
	Detail of Drug Sale License	Adress: M/s Aster Life Sciences, 32-Babar Block, New Garden Town, Lahore. Validity: 29-11-2019 Status: License to sell drugs as a Distributor.
	Name and address of manufacturer	M/s Panacea Biotec ltd, Village Malpur, Baddi, District Solan-173205, Himachal Pradesh, India.
	Name and address of marketing authorization holder	M/s Panacea Biotec ltd, Village Malpur, Baddi, District Solan-173205, Himachal Pradesh, India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 13999: 13-4-2018
	Fee including differential fee	PKR 100,000/-: 13-04-2018
	Brand Name +Dosage Form + Strength	PanimunBioral 50mg capsule(Soft gelatin)
	Composition	Each capsule contains: Cyclosporin…..50mg
	Finished Product Specification	USP
	Pharmacological Group	Calcineurin Inhibitors, ATC Code: L04AD01
	Shelf life	2Years
	Demanded Price	Rs. 3000/ 30 Capsules Rs. 5000/ 50 Capsules
	Pack size	6x5's blister strips
	International availability	USFDA Approved
	Me-too status	Gengraf Capsules by Abbott
	Detail of certificates attached	● Original Legalized COPP (No. of certificate MB/05/203/WHO/GMP/18-199) issued from Licensing Authority cum Controlling Authority Baddi-173205, Dis.Solan, Himachal Pradesh. And is valid upto 11-02-2020. The product is actually available on the market for use in the exporting country. ● Photocopy of legalized Certificate of GMP issued from Health and Family Welfare Department, Himachal Pradesh, Solan (State Drugs Controller). It is valid upto 25-11-2017. Certificate No. HFW-II|Drugs|302/05 (Vol-II) ● Letter of authorization issued on 26-09-2017 and is valid upto 30-April 2020, from M/s Panacea Biotec, India have submitted
	Remarks of the Evaluator. Firm has submitted 6 months accelerated stability study(40+-2 'C, 75RH+-5%) data and 12 months real-time (30+-2 'C, 70RH+-5%) stability study data , 24 months stability data at (25'C+-2'C, 60RH+-5%RH) of 5 batches. Initiation dates: Batch #108/094A (8-10-2005) Batch #0243/010 (8-10-2005) Batch #108/094B (8-10-2005) Batch #0243/018 (8-10-2005) Batch #0243/014 (8-10-2005)	
	Decision of 287th: Deferred for justification of claimed shelf life of 2 years, since firm has submitted long term stability (30+-2 ^{o}C, 70RH±5%) data of 12 months only. **Evaluation of PEC:** The firm has submitted long term stability data of 36 months of 3 batches and requested to consider our shelf-life as 36 months.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

837.	Name and address of Applicant	M/s Aster Life Sciences, 32-Babar Block, New Garden Town, Lahore.
	Detail of Drug Sale License	Adress: M/s Aster Life Sciences, 32-Babar Block, New Garden Town, Lahore. Validity: 29-11-2019 Status: License to sell drugs as a Distributor.
	Name and address of manufacturer	M/s Panacea Biotec ltd, Village Malpur, Baddi, District Solan-173205, Himachal Pradesh, India.
	Name and address of marketing authorization holder	M/s Panacea Biotec ltd, Village Malpur, Baddi, District Solan-173205, Himachal Pradesh, India.
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 14000: 13-4-2018
	Fee including differential fee	PKR 100,000/-: 13-04-2018
	Brand Name +Dosage Form + Strength	PanimunBioral 100mg capsule(Soft gelatin)
	Composition	Each capsule contains: Cyclosporin…..100mg
	Finished Product Specification	USP
	Pharmacological Group	Calcineurin Inhibitors, ATC Code: L04AD01
	Shelf life	2Years
	Demanded Price	Rs. 4800/ 30 Capsules Rs. 8000/ 50 Capsules
	Pack size	6x5's blister strips
	International availability	USFDA Approved
	Me-too status	Gengraf Capsules by Abbott
	Detail of certificates attached	• Original Legalized COPP (No. of certificate MB/05/203/WHO/GMP/18-198) issued from Licensing Authority cum Controlling Authority Baddi-173205, Dis.Solan, Himachal Pradesh. And is valid upto 11-02-2020. The product is actually available on the market for use in the exporting country. • Photocopy of legalized Certificate of GMP issued from Health and Family Welfare Department, Himachal Pradesh, Solan (State Drugs Controller). It is valid upto 25-11-2017. Certificate No. HFW-II|Drugs|302/05 (Vol-II) • Letter of authorization issued on 26-09-2017 and is valid upto 30-April 2020, from M/s Panacea Biotec, India have submitted
	Remarks of the Evaluator. • Firm has submitted 6 months accelerated stability study(40+-2 'C, 75RH+-5%) data and 12 months real-time (30+-2 'C, 70RH+-5%) stability study data , 24 months stability data at (25'C+-2'C, 60RH+-5%RH) of 5 batches. Initiation dates: Batch #108/094A (8-10-2005) Batch #0243/010 (8-10-2005) Batch #108/094B (8-10-2005) Batch #0243/018 (8-10-2005) Batch #0243/014 (8-10-2005)	
	Decision: Deferred for justification of claimed shelf life of 2 years, since firm has submitted long term stability (30+-2 ^{o}C, 70RH±5%) data of 12 months only. **Evaluation of PEC:** The firm has submitted long term stability data of 36 months of 3 batches and requested to consider our shelf-life as 36 months.	
	Decision: Approved as per Policy for inspection of Manufacturer abroad.	

Case No.04: Registration Applications of Drugs for which Stability Study Data is Submitted.

a. Exemption from Onsite Verification of Stability Data.

Exemption case					
Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability GMP Inspection Report Date & Remarks**	**REMARKS (IF ANY)**
838.	M/s Ferozsons Laboratories Limited, Nowshera, KPK	Artril tablets 49mg/51mg Each film coated tablet contains: Sacubitril……..49mg Valsartan as (Valsartan trisodiumhemipentahydrate)…….51mg Angiotensin II receptor Inhibitor and Neprilyn	Form 5-D Diary No. 1838 dated 24-8-2018 Rs. 50,000/- 20-08-2018, 1x14's, As per SRO	USFDA Approved Last inspection report 10-1-2018, Panel recommended for the issuance og GMP Certificate.	The firm has claimed Manufacturer's Specifications.

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Artril tablets 49mg/51mg		
Name of Manufacturer	M/s Ferozsons Laboratories Limited, Nowshera, KPK		
Manufacturer of API	M/s Nantong ChanyooPharmatech Co. Ltd. China.		
API Lot No.	201706001		
Description of Pack (Container closure system)	Alu/Alu film blister pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 75±5%RH		
Time Period	Accelerated: (6-months) Real Time: (6-months)		
Frequency	Accelerated: 0,1,2,3,4,6 months Real Time: 0,3,6 months		
Batch No.	SV tab-001	SV tab-002	SV tab-003
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	December-2017	December-2017	December-2017
Date of Initiation	December-2017	December-2017	December-2017
No. of Batches	3		
Date of Submission	20-08-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from Nantong ChanyooPharmatech 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.	GMP certificate issued from Nantong Chemical and Medical Industry is valid until 5-12-2019.
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

PREVIOUS REMARKS OF EVALUATOR[1]

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DECISION 275TH RB MEETING

Registration Board deliberated that it has been decided that onsite inspection for verification of data will be exempted as decided in instant meeting.

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter dated 19-10-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 276th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Registration Board approved "Invicta (Sofosbuvir 400mg + Velpatasvir 100mg)" Tablets in its 281st Meeting. • Dates of Inspection: o 16th March 2018.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has attested form-6 that permits the import of 2kg of Sacubitril + Valsartan from M/s Nantong ChanyooPharmatech Co. China.
3.	Documents for the procurement of reference standard and impurity standards.	• The firm has provided Invoice No. CY117235 Dated 26 Jun 2017 of importing Working standard and Impurity standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	GMP certificate issued from Nantong chemical and Medical Industry association and is valid until 5-12-2019.
5.	Mechanism for Vendor pre-qualification	Firm has given procedure for Induction of New Vendor for evaluation of vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	Photocopy of COA of Batch No. 201706001 by Nantong ChanyooPharmatechCo.Ltd is submitted. **Working standards**: Photocopy of COA of Batch No. WS201610001 is submitted. **Impurity Standard**: Photocopy of COA of impurity standards are submitted.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial Invoice from **M/s JRS Pharma, Germany dated 3-07-2017** for purchase Alufoil-bag. The firm has submitted photocopy of Commercial Invoice

<table>
<tr><td></td><td></td><td>from M/s Z.Son Enterprises, Peshawar dated 24-10-2017 for the purchase of 1kg LHPC.
The firm has submitted photocopy of Commercial Invoice from M/s B.B Mineral dated 26-08-2017 for purchase of Talcum powder.
The firm has submitted photocopy of Commercial Invoice from M/s Axis Chemicals, Karachi dated 2-10-2017 for purchase of Magnesium sterate,.
The firm has submitted photocopy of Commercial Invoice from M/s Colorcon, England dated 3-4-2017 for purchase of Opadry 200 yellow.</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 involved in product development with relevant experience.</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 written and authorized protocol for the development of product.</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 the following 03 Batches:
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg. Date</td></tr>
<tr><td>SV Tab-001</td><td>2500 Tablets</td><td>December-2017</td></tr>
<tr><td>SV Tab-002</td><td>2500 Tablets</td><td>December-2017</td></tr>
<tr><td>SV Tab-003</td><td>2500 Tablets</td><td>December-2017</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>Testing Frequency</th><th>No. of tablets consumed per test</th><th>Total number of tablets consumed</th><th>Remaining Quantity (Approx)</th></tr>
<tr><td>Trial # 01</td><td>For Accelerated
For Real Time</td><td></td><td>882</td><td>280</td></tr>
<tr><td>Trial # 02</td><td>For Accelerated
For Real Time</td><td></td><td>798</td><td>280</td></tr>
<tr><td>Trial # 03</td><td>For Accelerated
For Real Time</td><td></td><td>798</td><td>280</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>Now the firm has submitted photocopies of Log-it Chart (Humidity and temperature) starting from 31-Dec-2017 to30-Aug-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.</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 along with Stability Study Report & Supporting data for testing of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 12 Months stability real time report of API at 25’C+-2’C/ 60%+-5% and 6 Months accelerated Stability report at (40’C+_2’C/75%+-5%RH) Study Data of 03 Batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Certificates of Analysis for excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has submitted that we have used same excipients</td></tr>
</table>

<table>
<tr><td></td><td></td><td>as that of Innovator's product i.e. Entresto 49mg/51mg of Novartis.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative dissolution study of their product with Entresto tablet of M/s Novartis Pharmaceuticals. The details are as follows:
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Scotmann</th></tr>
<tr><td>• Brand name</td><td>• Entresto tablet</td><td>• Artril tablet</td></tr>
<tr><td>• Batch No.</td><td>• FX000010</td><td>• SVtab-001</td></tr>
<tr><td>• Mfg. date</td><td>•</td><td>• December-2017</td></tr>
</table>
• Comparative dissolution study was performed in following media(volume: 900ml, RPM= 50, Apparatus= Paddle):
• 0.1N HCl
• Acetate Buffer pH 4.5
• Phosphate buffer pH 6.8</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 as follows:
• Certificate of Compliance developed by Shimadzu Corporation, Analytical & Measurement Instruments Division 1 Nishinokyo-Kuwabaracho, Nakagyo-Ku, Kyoto, Japan
• The firm has submitted photocopy of Audit Trails.</td></tr>
<tr><td colspan="3">Remarks: The firm has submitted photocopy of 12 Months stability real time report of API at 25'C+-2'C/ 60%+-5% and 6 Months accelerated Stability report at (40'C+_2'C/75%+-5%RH) Study Data of 03 Batches.</td></tr>
<tr><td colspan="3">Decision 287th meeting: Registration Board deferred for submission of stability data of API from manufacturer as per Zone-IVA conditions.
Evaluation by PEC: The firm has now submitted long term stability data of API (30°C±2°C/65%RH±5%RH) for 18months of 3 batches.</td></tr>
<tr><td colspan="3">Decision: Registration Board decided to approve registration of Artril tablets 49mg/51mg by M/s Ferozsons Laboratories Limited, Nowshera, KPK. 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>

Evaluator PEC-VIII

Case No. 01 Registration Applications for Local Manufacturing of (Human) Drugs.

a. New cases

839.	Name and address of Manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd, K-219-A, SITE, Super Highway, Phase-II Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Pozwin tablet 15/2mg
	Composition	Each tablet contains: Pioglitazone (as hydrochloride)…15mg Glimepiride….2mg
	Diary No. Date of R&I & fee	DyNo.3788; 30-01-2018; Rs. 20,000/-
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA

	Me-too status	Glio-P Tablet of Macter International (Pvt) Ltd, Karachi
	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	Applied formulation is film coated tablet which is different from Reference product i.e. uncoated tablet. Submit Form 5, Master formulation & manufacturing method either in line with reference product along with required fee or evidence of reference product as film coated tablet. • *In response to above query firm has submitted revised Form 5 with change in composition & fee challan of Rs. 5000/- dated 12-03-2019for change in formulation.*
	Decision: Approved with USP specifications.	
840.	Name and address of Manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd, K-219-A, SITE, Super Highway, Phase-II Karachi, Pakistan.
	Brand Name + Dosage Form + Strength	Winralex Oral Drops10mg/ml
	Composition	Each ml contains: Escitalopram (as oxalate)…10mg
	Diary No. Date of R&I & fee	DyNo.3778; 30-01-2018; Rs. 20,000/-
	Pharmacological Group	Anti-Depressant
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(not verifiable)
	Me-too status	Depsit 10mg/ml Oral Drops of Genix Pharma Karachi
	GMP status	As recorded for above application
	Remarks of Evaluator	Reference product is approved as Escitalopram (as oxalate) 1 mg/ml drops, which is different form applied formulation i.e. Escitalopram (as oxalate) 10mg/ml. Submit form 5, master formulation, manufacturing method either in-line with reference product or evidence of approval of applied formulation.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.	
841.	Name and address of manufacturer / Applicant	WINTHROX LABORATORIES (PVT.) LTD. K-219-A, SITE, Superhighway, Phase-II Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Erinoc Tablets 50mg
	Composition:	Each sugar Coated Tablets contains: Eperisone hydrochloride……. 50mg
	Diary No. Date of R& I & fee:	Dy No. 3780; 30-01-18: Rs. 20,000
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in AIFA(Italy) Expose 50mg film coated tablets by ALFASIGMA S.P.A.
	Me-too status	Eperinal Tablets 50mg of Global Pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator	Reference product is Eperisone hydrochloride 50mg film coated tablet but you have applied with sugar coating, Submit form, master formulation, manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied formulation with sugar coating. • *In response to above query Firm has submitted evidence of applied drug product in AIFA which is also of Film coated tablet.*
	Decision: Approved with innovator's specification.	

842.	Name and address of manufacturer / Applicant	WINTHROX LABORATORIES (PVT.) LTD. K-219-A, SITE, Superhighway, Phase-II Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	COXWIN 60mg Tablets
	Composition:	Each Film Coated Tablets contains: Etoricoxib …….. 60mg
	Diary No. Date of R& I & fee Diary No:	Dy No. 3781; 30-01-18: Rs. 20,000
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Starcox 60 mg tab by Getz Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Monograph for test/analysis of applied formulation is not present in available USP & B.P.
	Decision: Approved with innovator's specification.	
843.	Name and address of manufacturer / Applicant	WINTHROX LABORATORIES (PVT.) LTD. K-219-A, SITE, Superhighway, Phase-II Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	POZWIN TABLETS
	Composition:	Each film coated tablet contains:- Glimepiride…… 2mg Pioglitazone as hydrochloride….. 30mg
	Diary No. Date of R& I & fee Diary No:	Dy. No. 3789; 30-01-18: Rs. 20,000
	Pharmacological Group	Combination of blood glucose lowering drugs
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duetact tablet by Takeda (USFDA Approved)
	Me-too status	Piozer G by Hilton
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Applied formulation is film coated tablet which is different from Reference product i.e. uncoated tablet. Submit Form 5, Master formulation & manufacturing method either in line with reference product along with required fee or evidence of reference product as film coated tablet. • *In response to above query firm has submitted revised Form 5 with change in composition & fee challan of Rs. 5000/- dated 12-03-2019for change in formulation.*
	Decision: Approved with USP specifications.	
844.	Name and address of manufacturer / Applicant	WINTHROX LABORATORIES (PVT.) LTD. K-219-A, SITE, Superhighway, Phase-II Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Tifany Syrup 1mg/5ml
	Composition:	Each 5ml contains: Ketotifen (as hydrogen fumarate) …1mg
	Diary No. Date of R& I & fee Diary No:	Dy No. 3779; 30-01-18: Rs. 20,000
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zaditen 1 mg / 5 ml oral solution by M/s SIGMA TAU, ANSM approved (as provided by the firm)

	Me-too status	Zatofen 1mg/5ml Syrup by M/s Novartis
	GMP status	As recorded for above application
	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 different from the applied formulation, in the sense that it Ketotifen (as fumarate) not as Ketotifen (as hydrogen fumarate).
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting	
845.	Name and address of manufacturer / Applicant	WINTHROX LABORATORIES (PVT.) LTD. K-219-A, SITE, Superhighway, Phase-II Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	FLEXABENZ-XR Capsule 30mg
	Composition:	Each capsule contains: Cyclobenzaprine hydrochloride …30mg (Extended release pellets) Source: Vision Pharmaceuticals
	Diary No. Date of R& I & fee:	Dy No. 3785; 30-01-18: Rs. 20,000
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Amrix extended release capsule of Teva Pharms intl, (USFDA)
	Me-too status	Emrix-SR of Getz Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
846.	Name and address of manufacturer / Applicant	WINTHROX LABORATORIES (PVT.) LTD. K-219-A, SITE, Superhighway, Phase-II Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	FLEXABENZ-XR Capsule 15mg
	Composition:	Each capsule contains: Cyclobenzaprine hydrochloride …15mg (Extended release pellets) Source: Vision Pharmaceuticals
	Diary No. Date of R& I & fee:	Dy No. 3784; 30-01-18: Rs. 20,000
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Amrix extended release capsule of Teva Pharms intl, (USFDA)
	Me-too status	Emrix-SR of Getz Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	

847.	**Name and address of manufacturer / Applicant**	M/s Seatal (Private) Limited, 45-km Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Avulus tablet 5mg
	Composition	Each film coated contains: Escitalopram(as oxalate)….5mg
	Diary No. Date of R& I & fee	Dy No.598; 30-12-2015; Rs.20,000/-
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors
	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.	Approved in USFDA
	Me-too status	Safepram tablet 5mg of Martin Dow
	GMP status	GMP inspection conducted on 25-10-2018concluded that firm is operating at good level of cGMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
848.	Name and address of manufacturer / Applicant	M/s Seatal (Private) Limited, 45-km Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Avulus tablet 10mg
	Composition	Each film coated contains: Escitalopram(as oxalate)….10mg
	Diary No. Date of R& I & fee	Dy No.599; 30-12-2015; Rs.20,000/-
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors
	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.	Approved in USFDA
	Me-too status	Safepram tablet 10mg of Martin Dow
	GMP status	GMP inspection conducted on 25-10-2018concluded that firm is operating at good level of cGMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
849.	Name and address of manufacturer / Applicant	M/s Seatal (Private) Limited, 45-km Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Avulus tablet 20mg
	Composition	Each film coated contains: Escitalopram(as oxalate)….20mg
	Diary No. Date of R& I & fee	Dy No.600; 30-12-2015; Rs.20,000/-
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors
	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.	Approved in USFDA
	Me-too status	Safepram tablet 20mg of Martin Dow
	GMP status	GMP inspection conducted on 25-10-2018concluded that firm is operating at good level of cGMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
850.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals, Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name+Dosage Form + Strength	Welnaz 200mg tablet
	Composition	Each Film Coated Tablet Contains: Voriconazole…200mg"
	Diary No. Date of R& I & fee	Dy. No. 3980; 31-01-18: Rs. 20,000

	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 in US-FDA
	Me-too status	Vorinaz 200mg Tablet of Atco Lab. Karachi
	GMP status	GMP inspection conducted on 16-09-2017 shows that firm is GMP compliant.
	Remarks of the Evaluator	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
851.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name+Dosage Form + Strength	Markfene 50mg Tablet
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R& I & fee	Dy. No. 3978; 31-01-18: Rs. 20,000
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form-5
	Finished Product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Clomidex Tablets 50 mg of CSH, Pharmaceuticals-North (Pvt.) Ltd.
	GMP status	GMP inspection conducted on 16-09-2017 shows that firm is GMP compliant.
	Remarks of the Evaluator	Firm has submitted "Tablet Hormone Section" approval letter. Is it a required manufacturing facility or it has to be manufactured in general section?
	Decision: 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.	
852.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Trevomol Tablets 325mg/37.5mg
	Composition	Each film coated tablet contains: Paracetamol….. 325mg Tramadol hydrochloride …37.5mg
	Diary No. Date of R& I & fee Diary No	Dy No. 24469; 30-01-18: Rs. 20,000
	Pharmacological Group	Analgesic/ Opioid Analgesics
	Type of Form	Form-5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Misadol Plus Tablet of Mission Pharma. Karachi
	GMP status	GMP inspection conducted on 26-07-2017shows that firm is operating at satisfactory level of cGMP.
	Remarks of the Evaluator.	
	Decision: Approved.	
853.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131, Industrial Estate, Hayatabad. Peshawar.
	Brand Name +Dosage Form + Strength	GLIMM-P Tablets 4mg/30mg
	Composition	Each film coated tablet contains:

		Glimepiride….4mg Pioglitazone (as hydrochloride) …30mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 24472; 14-12-18: Rs. 20,000
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Dazemep plus Tablet 4/30 of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	GMP inspection conducted on 26-07-2017shows that firm is operating at satisfactory level of cGMP.
	Remarks of the Evaluator	Applied formulation is film coated tablet which is different from Reference product i.e. uncoated tablet. Submit Form 5, Master formulation & manufacturing method either in line with reference product along with required fee or evidence of reference product as film coated tablet. • *Firm has submitted revised form 5 & Fee challan of Rupee 5000/- Dated 01-03-2019 for revision of formulation.*
	Decision: Approved.	
854.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Cardopin Plus Tablets 10mg/160mg/12.5mg
	Composition	Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan.....…160mg Hydrochlorothiazide…....12.5mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 24470; 14-12-17: Rs. 20,000
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's: 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
855.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131, Industrial Estate, Hayatabad. Peshawar.
	Brand Name +Dosage Form + Strength	GLIMM-P Tablets 2mg/30mg
	Composition	Each film coated tablet contains: Glimepiride….2mg Pioglitazone (as hydrochloride) …30mg
	Diary No. Date of R& I & fee Diary No	Dy. No. 24471; 14-12-18: Rs. 20,000
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Pio-Glee Tablet of M/s Rasco Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator	Applied formulation is film coated tablet which is different from Reference product i.e. uncoated tablet. Submit Form 5, Master

		formulation & manufacturing method either in line with reference product along with required fee or evidence of reference product as film coated tablet. • *Firm has submitted revised form 5 & Fee challan of Rupee 5000/- Dated 01-03-2019 for revision of formulation.*
	Decision: Approved.	
856	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Carelox 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Cefpodoxime (as proxetil) …100mg
	Diary No. Date of R& I & fee	Dy No. 6113: 19-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic
	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	Sefpotil 100mg Tablet of Lisko
	GMP status	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.
	Remarks of the Evaluator	
	Decision: Approved.	
857	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Scabex 5% Lotion
	Composition	"Each ml Contains: Permethrin…50mg"
	Diary No. Date of R& I & fee	Dy No. 6114: 19-02-18 ; Rs. 20,000
	Pharmacological Group	Pyrethrines, incl. synthetic compounds
	Type of Form	Form-5
	Finished product Specification	Innovator s Specifications
	Pack size & Demanded Price	60's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Plaveo Lotion 50mg/ml of Hiranis Karachi
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
858.	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 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Ebastine…20mg
	Diary No. Date of R& I & fee	Dy No. 6190: 19-02-18 ; Rs. 20,000
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not beconfirmed
	Me-too status	Lobastin Tablet 20mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection.

	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.	
859.	Name and address of manufacturer / Applicant	"M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi"
	Brand Name +Dosage Form + Strength	Clarimed 500mg Tablet
	Composition	"Each film coated tablet contains: Clarithromycin…500mg"
	Diary No. Date of R& I & fee	Dy No. 6270: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Claramet -500 Tablets of M/s Metro Pharmaceuticals.
	GMP status	GMP Inspection conducted on 12-12-2018 concluded that 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 USP Specifications.	
860.	Name and address of manufacturer / Applicant	"M/s CKD Pharmaceuticals Pakistan Private Limited. Plot No. 50/28, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Furaz Tablet 100mg
	Composition	"Each tablet contains: Furazolidone…100mg"
	Diary No. Date of R& I & fee	Dy No. 6466: 21-02-18 ; Rs. 20,000
	Pharmacological Group	Antidiarrheal
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's, 20's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA(but discountinued)
	Me-too status	Fydin Tablets of Healers Pharmaceuticals, Peshawar.
	GMP status	Firm is rated as GMP Compliant based on inspection conducted on 04/09/2018.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.	
861.	Name and address of manufacturer / Applicant	"M/s Welmed Pharmaceuticals Industries (Pvt) Ltd. Plot # 108, R:2, Industrial Estate Gadoon, Swabi"
	Brand Name +Dosage Form + Strength	Clarimed 250mg Tablet
	Composition	"Each film coated tablet contains: Clarithromycin…250mg"
	Diary No. Date of R& I & fee	Dy No. 6269: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA

	Me-too status	Claramet -250 Tablets of M/s Metro Pharmaceuticals.
	GMP status	GMP Inspection conducted on 12-12-2018 concluded that 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 USP Specifications.	
862.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Zodip-V Tablet 10/160mg
	Composition	"Each film coated tablet contains: Amlodipine(as besylate)…10mg Valsartan…160mg"
	Diary No. Date of R& I & fee	Dy No. 6185: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers 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	Co-Valzaar 10mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	GMP Inspection conducted on 03-01-2018 concluded that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Deferred for correct pharmacological group.	
863.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Zodip-V Tablet 5/160mg
	Composition	"Each film coated tablet contains: Amlodipine(as besylate)…5mg Valsartan…160mg"
	Diary No. Date of R& I & fee	Dy No. 6186: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers 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	Co-Valzaar 5mg/160mg Tablet of Vision Pharmaceuticals.
	GMP status	GMP Inspection conducted on 03-01-2018 concluded that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/ manufacturing facility.
	Decision: Deferred for correct pharmacological group.	
864.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Toplan Injection 200mg
	Composition	"Each vial contains: Teicoplanin…200mg"
	Diary No. Date of R& I & fee	Dy No. 6188: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5

	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Planin 200mg Injection of S.J &G. Fazul Ellahie, Karachi .
	GMP status	GMP Inspection conducted on 03-01-2018 concluded that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/ manufacturing facility. • Type of primary packaging material
	Decision: Deferred for the following: • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** • **Mention type of primary packaging material for applied formulation.**	
865.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Toplan Injection 400mg
	Composition	"Each vial contains: Teicoplanin…400mg"
	Diary No. Date of R& I & fee	Dy No. 6187: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Teicon Injection 400mg Of Al Habib Pharmacueticals Karachi
	GMP status	GMP Inspection conducted on 03-01-2018 concluded that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/ manufacturing facility. • Type of primary packaging material
	Decision: Deferred for the following: • **Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.** • **Mention type of primary packaging material for applied formulation.**	
866.	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	GlipVil Tablets 50mg
	Composition	"Each tablet contains: Vidagliptin…50mg"
	Diary No. Date of R& I & fee	Dy No. 5457: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Incriptin 50 mg Tablet of Martin Dow Ltd. Karachi
	GMP status	GMP Inspection conducted on 07-09-017 concluded that firm is operating at satisfactory level of GMP Compliance at the time of

		inspection.
	Remarks of the Evaluator	• Reference product in approved as uncoated tablet but you have applied for film coated 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 film coated tablet. ○ *Applicant has revised the formulation from coated to uncoated tablet with submission of Fee Rs. 5000/- Dated 0th May, 2019.*
	Decision: Approved with innovator's specification.	
867.	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"
	Brand Name +Dosage Form + Strength	VilGlip-M Tablet 50/850
	Composition	"Each film coated Tablet contains: Vildagliptin…50mg Metformin HCl…850mg"
	Diary No. Date of R& I & fee	Dy No. 5456: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Galmet 50mg/850mg Tablet of M/s Vision Pharmaceuticals.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
868.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Brand Name +Dosage Form + Strength	Aripra Tablet 20mg
	Composition	"Each tablet contains: Aripiprazole …20mg"
	Diary No. Date of R& I & fee	Dy No. 5511: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Apify 20mg Tablet of Akhai Karachi
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
869.	Name and address of manufacturer / Applicant	"M/s Novamed Pharmaceuticals (Pvt) Ltd, 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Pitava Tablet 2mg
	Composition	"Each film coated tablet contains: Pitavastatin (as calcium)…2mg"
	Diary No. Date of R& I & fee	Dy No. 5517: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-hyperlipidaemia
	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	Pitalip Tablets 2mg of Hilton Karachi
	GMP status	GMP Inspection conducted on 08-02-17 concluded that firm is operating at good level of GMP Compliance.
	Remarks of the Evaluator	
	Decision: Approved with Japanese Pharmacopoeia specifications.	
870.	Name and address of manufacturer / Applicant	"M/s Nova-Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial area. Karachi.
	Brand Name +Dosage Form + Strength	Cosiphen Syrup
	Composition	Each 5ml of syrup contains: Aminophylline…. 32mg Diphenhydramine hydrochloride….8mg Ammonium Chloride…30mg Menthol….. 0.98mg
	Diary No. Date of R& I & fee	Duplicate Dossier: Duplicate fee challan Rs. 20,000(25-05-17)
	Pharmacological Group	Anti-Tussive
	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	Could not be confirmed
	Me-too status	Broxol Syrup of Stanley Pharmaceuticals (Pvt) Ltd.
	GMP status	Panel Inspection for renewal of DML conducted on 28-02-19 recommends renewal of DML.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.	
871.	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	Cosiphen DM Syrup
	Composition	Each 5ml of syrup contains: Diphenhydramine hydrochloride….5mg Dextrometharphan Hydrobromide…. 6.25mg
	Diary No. Date of R& I & fee	Duplicate Dossier: Duplicate fee challan Rs. 20,000(23-05-17)
	Pharmacological Group	Anti-Tussive
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Xatus D Syrup of Asian Continental (Pvt.) Ltd Karachi
	GMP status	Panel Inspection for renewal of DML conducted on 28-02-19 recommends renewal of DML.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.	
872.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd, Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK **By** M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa"
	Brand Name +Dosage Form + Strength	Livi 2.5mg tablet
	Composition	"Each tablet contains: Tibolone…2.5mg"
	Diary No. Date of R& I & fee	Dy.No 5558 dated 15-02-2018 Rs. 50,000/- Dated 15-02-2018
	Pharmacological Group	Estrogens
	Type of Form	Form-5

	Finished product Specification	BP Specifications
	Pack size & Demanded Price	28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Livial tablet of OBS (druginfosis)
	GMP status	As recorded for above application
	Remarks of the Evaluator	M/S. Aries Pharmaceuticals has submitted section approval letter for tablet (hormone) section.
	Decision: Approved. The Board further advised the manufacturer to get approval for steroidal hormone section from Licensing Division before issuance of Registration letter.	
873.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd, Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK **By** M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa"
	Brand Name +Dosage Form + Strength	Dinac Tablet 2mg/35mcg
	Composition	"Each film coated Tablet contains: Cyproterone Acetate…2mg Ethinyloestradiol…35mcg"
	Diary No. Date of R& I & fee	Dy.No 5560 dated 15-02-2018 Rs. 50,000/- Dated 15-02-2018
	Pharmacological Group	Estrogens
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	21's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Acne-Heal Tablet of OBS, Pak Karachi
	GMP status	As recorded for above application
	Remarks of the Evaluator	M/S. Aries Pharmaceuticals has submitted section approval letter for tablet (hormone) section.
	Decision: Approved with innovator's specification. The Board further advised the manufacturer to get approval for steroidal hormone section from Licensing Division before issuance of Registration letter.	
874.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd, Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK **By** M/s Aries Pharmaceuticals, 1-W, Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa"
	Brand Name +Dosage Form + Strength	Safe 10mg Tablets
	Composition	"Each film coated tablet contains: Dydrogesterone…10mg"
	Diary No. Date of R& I & fee	Dy.No 5559 dated 15-02-2018 Rs. 50,000/- Dated 15-02-2018
	Pharmacological Group	Estrogens
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Danilon 10mg Tablet of Sami
	GMP status	As recorded for above application
	Remarks of the Evaluator	M/S. Aries Pharmaceuticals has submitted section approval letter for tablet (hormone) section. Clarification regarding cis or trans form of Dydrogesterone.
	Decision: Registration Board deferred the case for clarification regarding Specifications of applied drug product as it is not present in BP.	
875.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd, Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK **By:** Skims Pharmaceuticals, 10/B Value Addition city,

		Khurrianwala, Faisalabad"
	Brand Name +Dosage Form + Strength	Levetram 100mg Syrup
	Composition	"Each ml contains: Levetiracetam…100mg"
	Diary No. Date of R& I & fee	Dy.No 5522 dated 15-02-2018 Rs. 50,000/- Dated 15-02-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Levixa 100mg/ml Oral Solution of High-Q Pharmaceuticals,
	GMP status	Verification of facility for grant of additional sections to M/S Skims Pharmaceuticals conducted on 19-01-2018 concluded that firm is operating at good level of CGMP compliance.
	Remarks of the Evaluator	M/s. Skims Pharmaceuticals has submitted section approval letter for Oral Liquid General section. Type of Primary Packaging material.
	Decision: Registration Board deferred the case for clarification regarding Type of Primary Packaging material of applied drug product.	
876.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Presto 200mg Capsule
	Composition	"Each capsule contains: Fenofibrate…200mg"
	Diary No. Date of R& I & fee	Dy.No 6261 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018
	Pharmacological Group	LIPID MODIFYING AGENTS, PLAIN
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Tegex 200mg Capsule of Helix Pharmaceuticals Karachi
	GMP status	GMP Inspection conducted on 03-11-17 concluded that firm is operating at good level of GMP Compliance
	Remarks of the Evaluator	
	Decision: Approved with USP Specifications.	
877.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Lozan Tablet 40mg
	Composition	"Each enteric coated tablets contains: Pantoprazole (as sodium sesquihydrate)…40mg"
	Diary No. Date of R& I & fee	Dy.No 6260 dated 20-02-2018 Rs. 20,000/- Dated 20-02-2018
	Pharmacological Group	PPI
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's, 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cantrofast Tablets 40mg of M/s Candid Pharmaceuticals
	GMP status	GMP Inspection conducted on 03-11-17 concluded that firm is operating at good level of GMP Compliance
	Remarks of the Evaluator	
	Decision: Approved with USP specification.	

878.	Name and address of manufacturer / Applicant	"M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan"
	Brand Name +Dosage Form + Strength	Blufen 200mg Suspension
	Composition	"Each 5ml contains: Ibuprofen…200mg"
	Diary No. Date of R& I & fee	Dy.No 5494 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	60ml, 90ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Brofanic DSOral liquid suspension of M/s Regal Pharmaceuticals.
	GMP status	GMP Inspection conducted on 07-04-2018concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator	2% overage
	Decision:Deferred for justification on scientific grounds regarding addition of 2% overage in master formulation.	
879	Name and address of manufacturer / Applicant	M/s. Scilife Pharma Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi.
	Brand Name +Dosage Form + Strength	Zoptra tablet 40mg
	Composition	Each delayed release tablet contains: Pantoprazole (as sodium sesquihydrate)……40mg
	Diary No. Date of R& I & fee	Dy. No.3943; 24-05-2017; Rs.20,000/-
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Cantrofast Tablets 40mg of Candid Pharmaceuticals,
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with USP specification.	
880	Name and address of manufacturer / Applicant	M/s. Scilife Pharma Plot No. FD-57/58-A2, Korangi Creek Industrial Park, Karachi.
	Brand Name +Dosage Form + Strength	Zoptra tablet 20mg
	Composition	Each delayed release tablet contains: Pantoprazole (as sodium sesquihydrate)……20mg
	Diary No. Date of R& I & fee	Dy. No.3943; 24-05-2017; Rs.20,000/-
	Pharmacological Group	PPIs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	14's, 20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Cantrofast Tablets 20mg of Candid Pharmaceuticals,
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with USP specification.	
881.	Name and address of manufacturer / applicant	M/s Amson Vaccines & Pharma (Pvt) Ltd. Plot No. 154, Insdustrial Triangle, Kahuta Road, Islamabad Pakistan.

	Brand Name + Dosage Form + Strength	Osso-D Suspension 60ml / 120ml
	Composition	Each 5ml Contains Ossien Minerl Complex (Microcystalline Hydroxyapatite complex)…400mg + Vitamin D … 400IU
	Diary No. Date of R&1 & fee	Duplicate dossier
	Pharmacological Group	Minerals And Electrolytes
	Type of Form	Form-5
	Finished product and specification	AMSON SPECS
	Pack size and demanded price	60ml /120ml in PET bottle/AS per policy of DRAP
	Approval status of product in reference regulatory authorities	--
	Me too status	Intig D Suspension SAMI Pharmacuticals
	Remarks of the evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.	
882.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	IND-AIR Dry Powder Inhaler 150mcg
	Diary No. Date of R& I & fee	Diary No: 15331: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Indacaterol(as maleate)…. 150mcg
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in TGA
	Me-too status	Onbrez Breezhaler 150mcg Inhalation of Novartis Pharma
	GMP status	17-01-2019: Grant of Section/Facility and Regularization.
	Remarks of the Evaluator.	
	Decision: Registration Board decided to defer the case for further deliberation.	
883.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	BUD-AIR Dry Powder Inhaler 100/6mcg
	Diary No. Date of R& I & fee	Diary No: 15336: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Budesonide…. 100mcg Formoterol fumarate….6mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Canada (MHRA)
	Me-too status	Venticort Rotacaps 100mcg+6mcg Capsule of Macter Intr.
	GMP status	As recorded for above application

	Remarks of the Evaluator.	Reference product is powder for inhalation which is different from applied formulation i.e. Rota cap for inhalation..
	Decision: Registration Board decided to defer the case for further deliberation.	
884.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	BUD-AIR Dry Powder Inhaler 400/6mcg
	Diary No. Date of R& I & fee	Diary No: 15328: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Budesonide…. 400mcg Formoterol fumarate dihydrate….6mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Canada (MHRA)
	Me-too status	Venticort Rotacaps 100mcg+6mcg Capsule of Macter Int.
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Reference product is powder for inhalation which is different from applied formulation i.e. Rota cap for inhalation.
	Decision: Registration Board decided to defer the case for further deliberation.	
885.	Name and address of manufacturer / Applicant	M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Oxytide-F Dry Powder Inhaler 50/100mcg
	Diary No. Date of R& I & fee	Diary No: 15327: 15-09-17; Rs: 20,000/-
	Composition	Each Rota capsule contains: Salmeterol Xinafoate…. 50mcg Fluticasone propionate….100mcg
	Pharmacological Group	Long acting beta-2-adrenoreceptor agonists/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	28's, 60's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA & TGA
	Me-too status	Seretide Accuhaler 50/100mcg of GSK
	GMP status	As recorded for above application
	Remarks of the Evaluator.	.
	Decision: Registration Board decided to defer the case for further deliberation.	
886..	Name and address of Manufacturer / Applicant	M/s Welmark Pharmaceuticals Contract manufactured by M/s. Weatherfolds Pharmaceuticals
	Brand Name+Dosage Form+Strength	Stop 750 mcg tablet
	Composition	Each tablet contains: Levenorgestral… 750mcg
	Diary No. Date of R&I & fee	DyNo.3977; 31-01-2018; Rs. 20000/-

	Pharmacological Group	Contraceptives
	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	Could not be confirmed
	Me-too status	Emkit of Zafa pharmaceuticals (drug infosis)
	GMP status	GMP inspection of M/S. weatherfold conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	Evidence of section approval is required.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.** • **Evidence of approval of required manufacturing facility for applied formulation.**	

b. DEFERRED CASES:

887.	Name and address of Manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals Plot No.527-Sunder Industrial Estate, Lahore
	Brand Name+DosageForm+Strength	Dopridone Oral Suspension 5mg
	Composition	Each 5ml contains: Domperidone…5mg
	Diary No. Date of R&I & fee	Duplicate Dossier : Photocopy Of Fee Challan Of Rupee Rs.20,000/- Dated 05-07-17
	Pharmacological Group	Dopamine D2-receptor antagonist
	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	Epodom Suspension of Atlantic Pharmaceutical (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	
	Previous Decision	Registration Board in its 287th meeting deferred the case for the following: For clarification of primary container closure system for applied formulation.
	Evaluation by PEC	Firm has submitted following: • Firm opted for amber glass bottle for the applied formulation. • Fee challan of Rupee 5000/- dated, 22-03-19.
	Decision: Approved with innovator's specifications.	
888.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quid-e-azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form+ Strength	Namsal Injection 0.009g/ml
	Diary No. Date of R& I & fee	Diary No: 9434: 20-07-17; Rs: 20,000/-
	Composition	Each ml contains: Sodium Chloride…. 0.009gm
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	40ml,50ml,100ml ; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Flow NS IV Infusion Injectable of Mediflow (100ml)
	GMP status	GMP inspection conducted on 18-05-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Separate application for each volume. Mention type of primary packaging material. (Applicant has selected the filled volume "100ml" & type I glass as container closure system).
	Previous Decision	Registration Board in its 283rd meeting deferred the case for the following: Deferred for confirmation whether manufacturing facility of Liquid injectables is approved for " Small Volume Parenterals" or " Large Volume Parenterals"

Evaluation by PEC:

Firm has replied as follow:

Please note that we already hold registration of our different liquid injections with different pack sizes including 1ml, 3ml, 50ml,100ml, 250ml, 300ml, for your ready reference following documents are attached:

- Approval of our liquid Injection section.
- Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml.
- Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size.
- Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size.
- Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size.
- Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size.

Sr. No.	Reply of the Firm	Evaluation by PEC:
1	Approval of our liquid Injection section.	Applicant has submitted photocopy of Letter of CLB bearing a number No.F.1-65/84- Lic(Vol-II)(M-227)
2	Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml.	Applicant has submitted Photocopy of Registration Letter dated 16th of March 2004, for Adios Injection (100ml), Neumo Injection (100ml), Quash Injection (50ml, 100ml).
3	Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size.	Firm has submitted Photocopy of Registration Letter dated 09th of May 2017, for Palzic Injection (250ml).
4	Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size.	Firm has submitted Photocopy of Registration Letter dated 08th of January 2018, for Volinza Injection (300ml).
5	Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size.	Firm has submitted Photocopy of Registration Letter dated 24th of October 2017, for Zwitter Injection (3ml).
6	Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size.	Firm has submitted Photocopy of Registration Letter dated 18th of August 2011, for Zyster Injection (1ml).

Decision: Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility & equipment for applied drug product from Licensing Divisions.

889.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quid-e-azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name+Dosage Form + Strength	Namsal Injection 0.009g/ml
	Diary No. Date of R& I & fee	Diary No: 9432: 20-07-17; Rs: 20,000/-
	Composition	Each ml contains: Sodium Chloride…. 0.009gm
	Pharmacological Group	Electrolyte

	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2ml,5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Engsol Injection 0.90% w/v of English pharma(5ml)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Separate application for each applied volume. Mention type of primary packaging material. (Applicant has selected the filled volume "5ml" & type I glass as container closure system).
	Previous Decision	Registration Board in its 283rd meeting deferred the case for the following: Deferred for confirmation whether manufacturing facility of Liquid injectables is approved for " Small Volume Parenterals" or " Large Volume Parenterals"
	Evaluation by PEC: Firm has replied as follow: Please note that we already hold registration of our different liquid injections with different pack sizes including 1ml, 3ml, 50ml,100ml, 250ml, 300ml, for your ready reference following documents are attached: • Approval of our liquid Injection section. • Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml. • Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size. • Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size. • Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size. • Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size.	
	Decision: Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility& equipment for applied drug product from Licensing Divisions.	
890.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quid-e-azam Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name+Dosage Form + Strength	Namsal Injection 0.009g/ml
	Diary No. Date of R& I & fee	Diary No: 9433: 20-07-17; Rs: 20,000/-
	Composition	Each ml contains: Sodium Chloride…. 0.009gm
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml,20ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Engsol Injection 0.90% w/v of English Pharma(10ml)
	GMP status	GMP inspection conducted on 18-05-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Separate application for each applied volume. Mention type of primary packaging material. (Applicant has selected the filled volume "10ml" & type I glass as container closure system).
	Previous Decision	Registration Board in its 283rd meeting deferred the case for the following: Deferred for confirmation whether manufacturing facility of Liquid injectables is approved for " Small Volume Parenterals"

		or " Large Volume Parenterals"
	Evaluation by PEC: Firm has replied as follow: Please note that we already hold registration of our different liquid injections with different pack sizes including 1ml, 3ml, 50ml,100ml, 250ml, 300ml, for your ready reference following documents are attached: • Approval of our liquid Injection section. • Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml. • Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size. • Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size. • Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size. • Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size	
	Decision:Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility& equipment for applied drug product from Licensing Divisions.	
891.	Name and address of Manufacturer / Applicant	M/s. Danas Pharmaceuticals, 312, industrial triangle, Kahuta Road, Islamabad.
	Brand Name+DosageForm+Strength	Pequine tablets 75mg
	Composition	Each film coated tablet contains: Quetiapine (as fumarate)….75 mg
	Diary No. Date of R&I & fee	DyNo.9095; 18-07-2017; Rs. 20000/-
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	3×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not submitted
	Me-too status	Not submitted
	GMP status	Certificate of GMP is issued to the firm based on inspection conducted on 03-10-2017 valid for a period of one year.
	Remarks of Evaluator	Firm has claimed Manufacturer specifications but the applied formulation exist in USP. Firm has submitted that 75mg is a typographical error, kindly read the strength as 25mg instead of 75mg as 75mg is not available in reference agencies, hence corrected strength is 25mg.
	Previous Decision	Registration Board in its meeting deferred the case for Submission of fee for revision of formulation.
	Evaluation by PEC	Applicant has submitted Fee challan of Rupee 5000/- dated 25-02-2019 for revision of formulation.
	Decision: Registration Board decided to reject the applied drug product after taking the history of case into account.	
892.	Name and address of manufacturer / Applicant	M/s. Danas Pharmaceuticals, 312, industrial triangle, Kahuta Road, Islamabad.
	Brand Name+Dosage Form + Strength	Sidik tablet 250mg
	Diary No. Date of R& I & fee	Diary No: 9088: 08-07-17; Rs: 20,000/-
	Composition	Each tablet contains: Sodium fusidate…. 250mg
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack size & Demanded Price	2×10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA(uncoated tablet)
	Me-too status	Fucidin of LEO Pharm

	GMP status	Certificate of GMP is issued to the firm based on inspection conducted on 03-10-2017 valid for a period of one year.
	Remarks of the Evaluator	Applicant has revised the formulation from film coated to uncoated tablet, which is in line with reference product without submission of fee.
	Previous Decision	Registration Board in its meeting deferred the case for submission of fee for revision of formulation from Sodium fusidate 250mg film coated tablet to Sodium fusidate 250mg uncoated tablet.
	Evaluation by PEC	Applicant has submitted Fee challan of Rupee 5000/- dated 07-01-2019 for revision of formulation.
	Decision: Deferred for evidence of approval of required manufacturing facility as the applied drug product is a steroidal medication.	
893.	Name and address of Manufacturer / Applicant	M/s. Searle IV infusion, 1.5 km Raiwind Road, Manga Mandi Lahore
	Brand Name+Dosage Form+Strength	Tenorains 300mg Tablet
	Composition	Tenofovir disproxil fumarate….300mg
	Diary No. Date of R&I & fee	Dy.No.8939; 17-07-2017; Rs. 20,000/-
	Pharmacological Group	Nucleoside reverse transcriptase inhibitors
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	30's ; Rs.3450/- or As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Viread 300mg tablet of Ferozsons laboratories limited
	GMP status	GMP inspection conducted on 27-02-2018 with conclusive remarks that firm is GMP compliant
	Remarks of Evaluator	
	Previous decision	Registration board in its 283rd meeting deferred the case for the correction of label claim as per reference product.
	Evaluation by PEC	Applicant has submitted that the label claim of applied drug product is same to that of reference product.
	Decision: Approved with international Pharmacopoeia Specifications.	

Case no. 02 Registration Applications of Newly Granted DML or New Section (Human).

a. New/Additional Section(s)& Remaining Molecules (if any).

Lyophilized Vials Injectable (General): Previously considered Molecules; 08(M-275, M-288)		
Now applied: Molecules: 01 Products: 03		
894.	Name and address of Manufacturer / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Colimate Lyophilized 500,0000 IU Injection
	Composition	"Each Vial Contains: Colistimethate Sodium…500,0000 IU"
	Diary No. Date of R&I & fee	Dy.No 18442 dated 21-05-2018 Rs.20,000/- 21-05-2018
	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	Could not be confirmed
	Me-too status	Could not be confirmed

	GMP status	NEW SECTION (Letter Issuance date: 11th April, 2017) Lyophilized Vials Injectables(general)
	Remarks of Evaluator	Type of primary packaging material.
	Decision: Deferred for the following: • **For evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **For evidence of applied formulation/ drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **For clarification regarding Type of primary packaging material for applied drug product.**	
895.	Name and address of Manufacturer / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Colimate Lyophilized 200,0000 IU Injection
	Composition	"Each Vial Contains: Colistimethate Sodium…200,0000 IU"
	Diary No. Date of R&I & fee	Dy.No 2686 dated 21-01-2019 Rs.20,000/- 16-01-2019
	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 MHRA
	Me-too status	Could not be confirmed
	GMP status	NEW SECTION (Letter Issuance date: 11th April, 2017) Lyophilized Vials Injectables(general)
	Remarks of Evaluator	
	Decision:Deferred for submission of stability studies both accelerated & real time for six month as per guidelines approved & reviewed by registration board in its 251st& 278th meeting respectively.	
896.	Name and address of Manufacturer / Applicant	M/s MTI Medical Pvt Ltd. 586-587, Sundar Industrial Estate, Lahore, Pakistan"
	Brand Name + Dosage Form + Strength	Colimate Lyophilized 100,0000 IU Injection
	Composition	"Each Vial Contains: Colistimethate Sodium…100,0000 IU"
	Diary No. Date of R&I & fee	Dy.No 20578 dated 07-06-2018 Rs.20,000/- 07-06-2018
	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 MHRA
	Me-too status	Colistat powder for Injection of Medisure Lab. Karachi.
	GMP status	NEW SECTION (Letter Issuance date: 11th April, 2017) Lyophilized Vials Injectables(general)
	Remarks of Evaluator	
	Decision:Approved.	
	Dry powder Injectable (General):	
	Previously considered Molecules; 08 (M-275, M-288)	
	Name and address of Manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name + Dosage Form + Strength	Tigezon 50mg Injection
897.	Composition	"Each Vial Contains: Tigecycline Lyophilized Powder…50mg"
	Diary No. Date of R&I & fee	Duplicate dossier Rs.20,000/- (duplicate dossier)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications

	Pack Size & Demanded Price	1's, 5's, 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Tilane 50mg Injection of S.J&G Karachi .
	GMP status	NEW SECTION (Letter Issuance date: 11th April, 2017) Lyophilized Vials Injectables(general)
	Remarks of Evaluator	
	Decision:Registration Board deferred the case wheather it has to considered on priority as the firm has changed his nomenclature from Wellness Pharmaceuticals to Horizon Healthcare (Pvt) Ltd.	

b. Deferred Cases New DML/New Section(s).

898.	Name and address of manufacturer/ Applicant	M/s Saffron Pharmaceutical 19 km, Sheikhupura Road, Faisalabad.
	Brand Name +Dosage Form+Strength	Karit DrySuspension125mg/5ml
	Diary No. Date of R&I &fee	DiaryNo:34120; 15/10/2018; Rs:20,000/-
	Composition	Each 5ml(when reconstituted)contains: Clarithromycin …125mg (granules for oral suspension)
	Pharmacological Group	Antibiotic(Macrolide)
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size &Demanded Price	30ml,50ml,60ml/As perSRO
	Approval status of production Reference Regulatory Authorities.	Biaxin granules for oral suspension 125mg/5mlbyM/s Abbvie, USFDA approved.
	Me-too status	Klarim Dry Suspension 125mg/5ml of Amrose Pharma
	GMP status	New Section (Letter Issuance date:)
	Remarks of the Evaluator.	Mention type of primary packaging material of applied formulation. • (Firm has mentioned amber glass bottle as container closure system for applied formulation) Firm is using imported granules for which following things are required: • GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions. • Differential fee Of Rupee 80,000/- required in case of imported pellets.
	Previous Decision:	Registration Board in its 287th meeting deferred the case 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	Firm has submitted fee challan of Rupee 80,000/- dated 01-03-2019 & stability studies in accordance with zone IVA conditions & GMP certificate of Zheijiang Zhongtong Pharmaceuticals.
	Decision: Approved.	
899.	Name and address of manufacturer/ Applicant	M/s Saffron Pharmaceutical 19 km, Sheikhupura Road, Faisalabad.
	Brand Name +Dosage Form+Strength	Karit DrySuspension250mg/5ml
	Diary No. Date of R&I &fee	DiaryNo:34121; 15/10/2018; Rs:20,000/-
	Composition	Each 5ml(when reconstituted)contains: Clarithromycin …250mg (granules for oral suspension)
	Pharmacological Group	Antibiotic(Macrolide)

	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size &Demanded Price	30ml, 60ml; Rs. 400/-, Rs. 600/-
	Approval status of production Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Rethro 250mg /5ml of M/s Regal Pharmaceuticals
	GMP status	New Section (Letter Issuance date:)
	Remarks of the Evaluator.	Mention type of primary packaging material of applied formulation. • (Firm has mentioned amber glass bottle as container closure system for applied formulation) Firm is using imported granules for which following things are required: • GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions. Differential fee of Rs.80,000/- required in case of imported pellets
	Previous Decision:	Registration Board in its 287th meeting deferred the case 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	Firm has submitted fee challan of Rupee 80,000/- dated 01-03-2019 & stability studies in accordance with zone IVA conditions & GMP certificate of Zheijiang Zhongtong Pharmaceuticals.
	Decision: Approved.	

Case No. 03: Registration Applications for Local Manufacturing of (Veterinary) Drugs.

a. New Cases.

900.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals, Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Cina-Wal Liquid
	Composition	"Each ml Contains: Enrofloxacin…75mg Sulphamethoxypiridazine…75mg Sulphamethazine…50mg Trimethoprim…25mg"
	Diary No. Date of R& I & fee	Dy No. 6244: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ML, 500ml: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	-
	Me-too status	Cina T.S Oral Suspension of M/S. Vety-Care, Rawalpindi
	GMP status	GMP Inspection conducted on 29-10-2018 concluded that firm is compliant to current Good manufacturing requirements with the need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator	
	Decision: Referred to expert group on veterinary drugs.	
901.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Fen-Wal Liquid
	Composition	"Each 100ml contains:

		Florfenicol…25g Colistin Sulphate…50 MIU"
	Diary No. Date of R& I & fee	Dy No. 6245: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ML, 500ml, 1Litre, 2.5Litre: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Flocol Liquid of M/s. D-maarson pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision:Approved with Innovator's Specifications.	
902.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Neo-Flox Powder
	Composition	"Each gm contains: Oxytetracycline hydrochloride…300mg Florfenicol…100mg Neomycin sulphate…150mg"
	Diary No. Date of R& I & fee	Dy No. 6247: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 10kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	E-Col of M/s. Evergreen (Reg.#081733) (From M-286th RB)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications.	
903.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Amar-Wal 98% Powder
	Composition	"Each 100g contains: Amantadine hydrochloride…98g"
	Diary No. Date of R& I & fee	Dy No. 6248: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 10kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Amantadine hydrochloride powder of M/s Evergreen (Reg.# 081735) (From M-285th RB)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications.	
904.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Tylo-Wal Powder
	Composition	"Each gm contains: Tylosin Tartrate…980mg"
	Diary No. Date of R& I & fee	Dy No. 6249: 20-02-18 ; Rs. 20,000

	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Tylotar-98 of M/s. Evergreen Reg. #081736 (From M-285th RB)
	GMP status	As recorded for above application
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided me-too is not verifiable.
	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, as the provided me-too is not verifiable.	
905.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Wal-Fen 25% Liquid
	Composition	"Each 100ml contains: Florfenicol…25g"
	Diary No. Date of R& I & fee	Dy No. 6242: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Florfenicol Oral Liquid of M/S. Attabak Pharmaceuticals, Islamabad.
	GMP status	As recorded for above application
	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, as the provided me-too is not verifiable.	
906.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Fenicol Oral Liquid
	Composition	Each 100ml contains: Florfenicol…10g Colistin sulphate…. 50MIU
	Diary No. Date of R& I & fee	Dy No. 6243: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Floro-C Oral Liquid Of M/S. D-Maarson Pharmaceuticals
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
907.	Name and address of manufacturer / Applicant	"M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur, KPK"

	Brand Name +Dosage Form + Strength	LC 10 Powder
	Composition	"Each 100gm powder contains: Lincomycin HCl …9gm Colistin Sulphate …80,000,000 IU."
	Diary No. Date of R& I & fee	Dy No. 5735: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm,1kg, 5kg,10kg,15kg,20kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	LC-100 Oral Powder Of M/S. Ras Pharma, Multan
	GMP status	GMP Inspection conducted on 07-09-2017concluded as follows: Observations/ Recommendations: "1- Improve quality assurance system as per GMP guidelines. 2- Develop annual product review system for marketed products. Overall firm was working under satisfactory level of GMP."
	Remarks of the Evaluator	
	Decision: Approved with Innovator's Specifications.	
908.	Name and address of manufacturer / Applicant	"M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur, Kpk"
	Brand Name +Dosage Form + Strength	LS Mox Powder
	Composition	"Each 100gm powder contains: Amoxicillin Trihydrate…20gm Lincomycin HCl…9gm Spectinomycin 2HCl…8.8gm"
	Diary No. Date of R& I & fee	Dy No. 5734: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Innovators Specifications
	Pack size & Demanded Price	10gm, 20gm, 30gm, 50gm, 100gm, 250gm, 500gm,1kg, 5kg,10kg,15kg,20kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	LC-100 Oral Powder Of M/S. Ras Pharma, Multan
	GMP status	As recorded for above application
	Remarks of the Evaluator	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. **Evaluation by PEC:** On recommendation of panel of experts, The CLB in its 253rd meeting held on May 15th-16th, 2017 has considered and approved the grant of Dry Penicillin Powder section(vet).
	Decision: Approved with innovator's specification.	
909.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Linco-Wal Powder (water soluble)
	Composition	"Each gm contains: Lincomycin hydrochloride…100mg Colistin Sulphate…800,000 IU"
	Diary No. Date of R& I & fee	Dy No. 5536: 15-02-18 ; Rs. 20,000

	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Colimycin Water Soluble Powder of Attabak Pharmaceutical Islamabad.
	GMP status	GMP Inspection conducted on 29-10-2018 concluded that firm is compliant to current Good manufacturing requirements with the need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
910.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Doxy-50 Powder (water soluble)
	Composition	"Each gm contains: Doxycycline HCl …500mg"
	Diary No. Date of R& I & fee	Dy No. 5535: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 25kg:Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Doxybak Powder of Attabak Pharmaceuticals Islamabad. (Each 100g Contain: Doxycycline HCl …….50gm)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
911.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	T-Dox Powder (water soluble)
	Composition	"Each 100gm contains: Doxycycline HCl …40mg Tylosin tartrate …20g"
	Diary No. Date of R& I & fee	Dy No. 5534: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 25kg:Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Dot Powder of Attabak Pharmaceutical, Islamabad.
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
912.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Waltin Liquid (oral liquid)
	Composition	"Each 100ml contains: Enrofloxacin …10g Colistin Sulphate …50 MIU"
	Diary No. Date of R& I & fee	Dy No. 5531: 15-02-18 ; Rs. 20,000

	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre:Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Enrotin solution of Attabak pharma Islamabad
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
913.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Menbro-60 Liquid (oral liquid)
	Composition	"Each ml contains: Bromhexine HCl …50mg Menthol …40mg"
	Diary No. Date of R& I & fee	Dy No. 5532: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre:Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Broman of D-Maarson (not verifiable)
	GMP status	As recorded for above application
	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.
	Decision: Approved with innovator's specification.	
914.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Enro-Mix Liquid (oral liquid)
	Composition	"Each 100ml Contains: Enrofloxacin…20gm Colistin Sulphate…50 MIU"
	Diary No. Date of R& I & fee	Dy No. 5533: 15-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre:Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Floxa-C Oral Solution Of "Baariq Pharmaceuticals,
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
915.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ever-Coc Water Soluble Powder
	Composition	"Each gm Contains: Amprollium hydrochloride…200mg Furaltadon hydrochloride …200mg Vitamin K3…5mg"
	Diary No. Date of R& I & fee	Dy No. 6120: 19-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotics/antibacterial

	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 500gm, 1kg, 5kg,10kg, 25kg : Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Wealcoc Powder Of M/S. Mallard Pharmaceutical, Multan
	GMP status	Panel Inspection conducted on 03-01-2018 for renewal of DML recommended renewal of DML.

Remarks of the Evaluator

Sr. No.	Remarks of the Evaluator	Reply of the firm
1	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Firm has Panel Inspection report for renewal of DML confirming liquid Oral (veterinary) & Dry Powder General section. **Dry powder general section does not contain the world veterinary with it.*

Decision:Registration Board decided to reject the applied drug product as Furaltadon hydrochloride is banned in many countries including EMA for use in livestock owing to its carcinogenic effects on humans.

916.	Name and address of manufacturer / Applicant	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Area, 20th km Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Terivet Plus Oral Suspension
	Composition	Each ml Contains: Trimethoprim.....…80mg Sulfadiazine…….....400mg
	Diary No. Date of R& I & fee	Dy No. 6121: 19-02-18 ; Rs. 20,000
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	-
	Me-too status	Sulzine oral suspension of ISIS Pharmaceuticals.
	GMP status	Panel Inspection conducted on 03-01-2018 for renewal of DML recommended renewal of DML.

Remarks of the Evaluator

Sr. No	Remarks of the Evaluator	Reply of the firm
1	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Firm has Panel Inspection report for renewal of DML confirming liquid Oral (veterinary) & Dry Powder General Section. **Dry powder general section does not contain the world veterinary with it.*

Decision: Approved with innovator's Specifications.

917.	Name and address of Manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name + Dosage Form + Strength	Colmox-20 Powder (Oral Powder)
	Composition	Each Kg contains: Amoxicillin trihydrate…....0.2kg Colistin sulphate…….....0.06kg
	Diary No. Date of R&I & fee	DyNo.3689; 29-01-2018; Rs. 20,000/-
	Pharmacological Group	Penicillin Antibiotic, Polymyxin Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	28g, 100g Alu sachet

		250g, 450g,500g,100g plastic jars 5kg,25kg Polythene bag: Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Technolan Water Soluble Powder of Vetworld Animal Health Company, Rawalpindi (500gm, 1000gm.)
	GMP status	Panel Inspection for Renewal of DML conducted on 09-11-2018 recommends renewal of DML bearing No. 000534 & grant of Bolus section in favour of M/s. A&K Pharmaceuticals & does not recommend Oral dry Powder (Penicillin) at present.

Remarks of Evaluator:

Sr. No.	Remarks of Evaluator:	Reply By the Firm.
1.	Approval of section/manufacturing facility (Penicillin dedicated facility) by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Our Penicillin Section for oral powders is under approval. When it will be approved we will submit the approval report. • *Applied formulation contains Penicillin antibiotic in it.*
2.	Submit quantity per grams for both APIs of applied formulation; furthermore submit quantity of Colistin sulphate in international (IU) units as well.	Each gram contains: Amoxicillin trihydrate… 200mg. Colistin sulphate….1200000IU.

Decision: Registration Board decided to reject the applied formulation as firm don't have required manufacturing facility for applied drug Product.

918.	Name and address of Manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name + Dosage Form + Strength	Levanew-400 Bolus (Oral Bolus)
	Composition	Each bolus contains: Levamisol hydrochloride…. 0.4g
	Diary No. Date of R&I & fee	DyNo.3697; 29-01-2018; Rs. 20,000/-
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	5's, 10's, 20's, 50's, 100's,: Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Leva 400 Bolus of Intervac (Pvt) Ltd (5 Bolus,10 Bolus,20 Bolus,50 Bolus)
	GMP status	As recorded for above application

Remarks of Evaluator:

Sr.#	Remarks of Evaluator	Reply of the firm
1	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Panel Inspection for Renewal of DML conducted on 09-11-2018 recommends renewal of DML bearing No. 000534 &*grant of Bolus section* in favour of M/s. A&K Pharmaceuticals & does not recommend Oral dry Powder (Penicillin) at present.

Decision: Deferred for evidence of approval of required manufacturing facility for applied formulation.

919.	Name and address of Manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name + Dosage Form + Strength	Levanew-600 Bolus (Oral Bolus)
	Composition	Each bolus contains: Levamisol hydrochloride…. 0.6g(600mg)
	Diary No. Date of R&I & fee	DyNo.3699; 29-01-2018; Rs. 20,000/-
	Pharmacological Group	Anthelmintic

	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	5's, 10's, 20's, 50's, 100's,: Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	VERNIL-600 Bolus of Star Laboratories Lahore (5 Bolus,10 Bolus, 50 Bolus)
	GMP status	As recorded for above application

Remarks of Evaluator:

Sr. No.	Remarks of Evaluator	Reply of the firm
1	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Panel Inspection for Renewal of DML conducted on 09-11-2018 recommends renewal of DML bearing No. 000534 *& grant of Bolus section* in favour of M/s. A&K Pharmaceuticals & does not recommend Oral dry Powder (Penicillin) at present.

Decision: Deferred for evidence of approval of required manufacturing facility for applied formulation.

920.	Name and address of Manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name + Dosage Form + Strength	Levanew-1125 Bolus (Oral Bolus)
	Composition	Each bolus contains: Levamisol hydrochloride…. 1.125g(1125mg)
	Diary No. Date of R&I & fee	DyNo.3699; 29-01-2018; Rs. 20,000/-
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	5's, 10's, 20's, 50's, 100's,: Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Primisol 1125 Bolus of Prix Pharmaceutica (Pvt) Ltd., Lahore (20's, 50's)
	GMP status	As recorded for above application

Remarks of Evaluator:

Sr.#	**Remarks of Evaluator**	**Reply of the firm**
1	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Panel Inspection for Renewal of DML conducted on 09-11-2018 recommends renewal of DML bearing No. 000534 &*grant of Bolus section* in favour of M/s. A&K Pharmaceuticals & does not recommend Oral dry Powder (Penicillin) at present.

Decision:Deferred for evidence of approval of required manufacturing facility for applied formulation.

921.	Name and address of Manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name + Dosage Form + Strength	Milko-Plus Minerals (Oral)
	Composition	Each kg Contains: Calcium…155 grams Phosphorus…135 grams Magnesium…55 grams Sodium…45 grams Iron…1 grams Zinc…3 grams Manganese…2 grams Copper…0.6 grams Cobalt…0.01 grams Iodine…0.04 grams

		Selenium…0.003 grams
	Diary No. Date of R&I & fee	DyNo.3688; 29-01-2018; Rs. 20,000/-
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	1kg,5kg,10kg,25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	L.S.Minerals Powder of Nawan Labs Karachi
	GMP status	As recorded for above application

Remarks of Evaluator:

Sr. No	Remarks of Evaluator:	Reply of the Firm
1.	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Panel Inspection for Renewal of DML conducted on 09-11-2018 recommends renewal of DML bearing No. 000534 &*grant of Bolus section* in favour of M/s. A&K Pharmaceuticals & does not recommend Oral dry Powder (Penicillin) at present.
2.	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as provided me too does not contain one of the ingredients of applied formulation i.e. "selenium" in it.	SP minerals Granules by7 Selmore Pharma, Lahore. Reg # 088154. • *Needs verification.*

Decision: Deferred for evidence of approval of required manufacturing facility for applied formulation.

922.	Name and address of Manufacturer / Applicant	M/s A & K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Faisalabad.
	Brand Name + Dosage Form + Strength	Milko-gold Minerals (Oral)
	Composition	Each kg Contains: Vitamin A…0.8 grams Vitamin D3…0.16 grams Vitamin E…0.38 grams Vitamin B2…1.25 grams Vitamin B12…0.001 grams Vitamin B3…6.25 grams Copper Sulphate…0.25 grams Magnesium Sulphate…25 grams Calcium Chloride…0.023 grams Zinc Sulphate…2.17 grams Maganese Sulphate…10 grams Potassium Iodide…0.5 grams Sodium Selenite…0.01 grams Dibasic Calcium Phosphate…150 grams Sodium Chloride…120 grams
	Diary No. Date of R&I & fee	DyNo.3687; 29-01-2018; Rs. 20,000/-
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	1kg,5kg,10kg,25kg(bags): Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	White Gold Powder of Leads Pharma (Pvt) Ltd.
	GMP status	As recorded for above application

Remarks of Evaluator:

Sr.	Remarks of Evaluator	Reply of the firm

	No.		
	1	Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Panel Inspection for Renewal of DML conducted on 09-11-2018 recommends renewal of DML bearing No. 000534 *& grant of Bolus section* in favour of M/s. A&K Pharmaceuticals & does not recommend Oral dry Powder (Penicillin) at present.
	2	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as provided me too contains some other ingredients in it.	Some other ingredients were added additionally like Vitamin B1 & vitamin B6 in the given Me too status after our application for registration of drug. However we are interested in the same formulation as follow: **Me Too:** White Gold Powder of Leads Pharma Reg No. 058842
	Decision: Deferred for the following: • **Evidence of approval of required manufacturing facility for applied formulation.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**		

Case No. 04: Registration Applications of Categories to be Considered on Priority.

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

i. Human

923.	Name and address of Applicant	Genix Pharma (Pvt) ltd. 44, 45-B Korangi Creek Road, Karachi, 75190, Pakistan.
	Detail of Drug Sale License	**Address:** Genix Pharma (Pvt) ltd. 44, 45-B Korangi Creek Road, Karachi, 75190, Pakistan. **Validity:** 23/05/2020 **Status:** Drug License by way of Wholesale
	Name and address of manufacturer	Yichang Humanwell Pharmaceutical Co., Ltd., No. 19 of Dallan road, Yichange Developing Zone, Hubei Province, China.
	Name and address of marketing authorization holder	Yichang Humanwell Pharmaceutical Co., Ltd., No. 19 of Dallan road, Yichange Developing Zone, Hubei Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.15723 Dated 27/04/2018
	Fee including differential fee	Rs. 50,000/- Dated 20/04/2018
	Brand Name +Dosage Form + Strength	Refent Injection 1mg
	Composition	Each vial contains: Remifentanil hydrochloride….1mg (freeze-dried powder for injection)
	Finished Product Specification	Innovator's specifications
	Pharmacological Group	Anaesthetic
	Shelf life	2 years
	Demanded Price	As per SRO
	Pack size	5's: As Per SRO
	International availability	Approved in US-FDA
	Me-too status	N/A
	Detail of certificates attached	**Origional legalized CoPP:** Certificate No: 20170063

		Certified by: Hubei Food & Drug Administration No. 19 Gongzheng Road Wu Chang District, Wuhan City, China. Issued date: 18/12/2017 Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to GMP as recommended by WHO as per CoPP. **legalized Free sale Certificate:** Certificate No: 2017-63 Certified by: Hubei Food & Drug Administration. Issued date: 06/12/2017 Validity: 2years **legalized GMPCertificate:** Certificate No: HB20170318 Certified by: Hubei Province Food & Drug Administration. Issued date: 04/02/2017 Validity: valid until 03-02-2022 Letter of authorization: Genix Pharma (Pvt) ltd & Yichang Humanwell Pharmaceutical.
	Remarks of the Evaluator.	Submit stability Studies both accelerated & real time of three batches of applied formulation as per Zone VI-A conditions as submitted stability studies are not according to Zone IVa conditions. (Applicant has submitted that Product is unstable at 30C it has to be stored between 2- 25C) they have submitted stability study data at following conditions: Real Time: $25^{o}C \pm 2^{o}C$ / 60% ± 5%RH Accelerated:$30^{o}C \pm 2^{o}C$ / 65% ± 5%RH
	Decision: Deferred for the following: **For clarification regarding storage conditions of Innovator product.** **For submission of stability study data both accelerated & real time for two more batches of applied drug product as stability studies data for only one batch is submitted.**	

Case No. 05: Registration Applications of Import Cases:

a. New Cases (Human)

924	Name and address of Applicant	M/s We Care (Revolution in Health care) House No. 275 Street No.55 Sector I-8/3, Islamabad.
	Detail of Drug Sale License	Address: Flat No B-6, 2nd Floor, Block D-12, Sector G-8, Markaz Islamabad. Validity: 02-12-2020 Status: Licence To Sell Drugs In A Whole Sale Distribution.
	Name and address of manufacturer	M/s Shenzhen South China Pharmaceutical (NCPC) Co., Ltd. D Building No. 2, Industrial Park Of Xiashijia, Jiangshi, District: Gongming Town.,Guangming New Zone, Shenzhen, P.R. China
	Name and address of marketing authorization holder	M/s SinoPharm International Co., Ltd. Building 12, No. 899, Zu Chongzhi Rd., Zhangjiang Hi-Tech Park, Pudong District, Shanghai, 201203, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.24464 Dated 14/12/2017
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form +	Biopenem Injection

	Strength	
	Composition	Each vial contains: Meropenem for Injection… 0.5gm (500mg)
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Antibiotic
	Shelf life	36 months
	Demanded Price	De-Controlled
	Pack size	1gm, 500gm, 1kg
	International availability	Approved in US-FDA
	Me-too status	Xepime 0.5gm Injection IV Each vial contains:- Meropenem (as Trihydrate)…0.5gm of Macter International (Pvt) Ltd , Karachi
	Detail of certificates attached	**Original legalized GMP Certificate:** **Certificate No.** GD20170711 **Certified by:** China Food & Drug Administration **Issued date:** 28/06/2022 **Free sale in exporting country:** Confirms the free sale of the product in exporting country. **GMP:** The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Original Legalised Letter of authorization** M/s We Care & M/s Shenzhen North China **Validity**:.

Remarks of the Evaluator:

Sr. No.	Remarks of the Evaluator:	Reply of the firm
1	Explain the difference of Name of Manufacturer on Letter of Authorization i.e. Shenzhen North China & on Form 5 Shenzhen South China.	
2	Reference product is approved as meropenem (as trihydrate) 0.5gm Powder for Injection or Infusion which is different from applied formulation i.e. meropenem 0.5gm Powder for Injection or infusion. Clarify/ Justify.	Firm has claimed it as meropenem (as trihydrate) 0.5gm injection.
3	Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.	Type I glass
4	Submit copy of valid DSL of the applicant.	Applicant has submitted DSL with Following Information: **Address:** Flat No B-6, 2nd Floor, Block D-12, Sector G-8, Markaz Islamabad. **Validity:** 02-12-2020 **Status:** Licence To Sell Drugs In A Whole Sale Distribution

Decision: Approved.

925	Name and address of Applicant	M/s We Care (Revolution in Health care) House No. 275 Street No.55 Sector I-8/3, Islamabad.
	Detail of Drug Sale License	Address: Flat No B-6, 2nd Floor, Block D-12, Sector G-8, Markaz Islamabad. Validity: 02-12-2020 Status: Licence To Sell Drugs In A Whole Sale Distribution
	Name and address of manufacturer	M/s Shenzhen South China Pharmaceutical (NCPC) Co., Ltd. D Building No. 2, Industrial Park Of Xiashijia, Jiangshi, District: Gongming Town.,Guangming New Zone, Shenzhen, P.R.

	China
Name and address of marketing authorization holder	M/s SinoPharm International Co., Ltd. Building 12, No. 899, Zu Chongzhi Rd., Zhangjiang Hi-Tech Park, Pudong District, Shanghai, 201203, China.
Name of exporting country	China
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No.24465 Dated 14/12/2017
Fee including differential fee	Rs. 100,000/-
Brand Name +Dosage Form + Strength	Biopenem Injection
Composition	Each vial contains: Meropenem for Injection… 1gm (1000mg)
Finished Product Specification	USP Specifications
Pharmacological Group	Antibiotic
Shelf life	24months (Stability studies submitted according to Zone IVA conditions)
Demanded Price	De-Controlled
Pack size	
International availability	Approved in US-FDA
Me-too status	Xepime 1gm Injection IV Each vial contains:- Meropenem (as Trihydrate)…1gm of Macter International (Pvt) Ltd , Karachi
Detail of certificates attached	**Copy of Original legalized GMP Certificate:** **(for Meropenem 0.5gm Injection)** **Certificate No.** GD20170711 **Certified by:** China Food & Drug Administration **Issued date:** 28/06/2022 **Free sale in exporting country:** Confirms the free sale of the product in exporting country. **GMP:** The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Original Legalised Letter of authorization** M/s We Care & M/s Shenzhen North China **Validity**:

Remarks of the Evaluator:

Sr.#	Remarks of the Evaluator	Reply of the firm
1	Explain the difference of Name of Manufacturer on Letter of Authorization i.e. Shenzhen North China & on Form 5 Shenzhen South China.	
2	Reference product is approved as meropenem (as trihydrate) 1gm Powder for Injection or Infusion which is different from applied formulation i.e. meropenem 1gm Powder for Injection or infusion. Clarify/Justify.	Firm has claimed it as meropenem (as trihydrate) 0.5gm injection.
3	Mention type of primary packaging material of applied formulation whether it is Type I, Type II & Type III glass container.	Type I glass
4	Submit Original legalized GMP Certificate & Free sale Certificate or Original legalized COPP, for the applied strength i.e. " meropenem 1gm powder for injection or Infusion". Of applied formulation as attached documents are of another strength.	Firm submitted legalized COA instaed of COPP.
5	Submit copy of valid DSL of the applicant.	Applicant has submitted DSL with Following Information: **Address:** Flat No B-6, 2nd Floor, Block D-12, Sector G-8, Markaz Islamabad.

			Validity: 02-12-2020 **Status:** Licence To Sell Drugs In A Whole Sale Distribution
	Decision: Deferred for submission of Original Legalized COPP for applied drug product.		
926	Name and address of Applicant	M/s Network Marketing Services, 14C (Commercial) P.C.H.S., Defence Road, Lahore.	
	Detail of Drug Sale License	Address: Validity: Status:	
	Name and address of manufacturer	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu,China	
	Name and address of marketing authorization holder	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu, China	
	Name of exporting country	China	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy. No. 1774 Dated 12/01/2018	
	Fee including differential fee	Rs. 100,000/-	
	Brand Name +Dosage Form + Strength	Angiovision Injection	
	Composition	Each ml contains: Iohexol…. 755mg (equivalent to 350mg of iodine)	
	Finished Product Specification	USP Specifications	
	Pharmacological Group	Water-soluble, nephrotropic, low osmolar X-ray contrast media/ Non Ionic Contrast Media	
	Shelf life	24months (Stability studies submitted according to Zone IVA conditions)	
	Demanded Price	As per SRO	
	Pack size	100ml (Iohexol 77.5g equivalent to 350mg of iodine)	
	International availability	Approved in US-FDA (OMNIPAQUE 350 mg iodine/mL (755 mg of iohexol/mL)	
	Me-too status	Iobrix-350 Injection Of Hoffmann Human Health Pak Ltd Lahore	
	Detail of certificates attached	**Original legalized COPP:** Certificate No: F-2016-06001. Certified by: Jiangsu Food & Drug Administration, China. Date for Issuance: June 7, 2016. Validity: Two Years From Issuance (it is not valid now). **Free sale in exporting country:** Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Original legalized GMP Certificate:** Certificate No. CN20140268 Certified by: China Food & Drug Administration Date for Issuance: 05/06/2014 Valid till**:** 05/06/2019	
	Remarks of the Evaluator	Submit Stability study of one more batch of applied formulation both accelerated & real time conducted in accordance with zone IV-A conditions as you have submitted stability studies of two batches of applied formulation. Submit Valid Original legalized COPP as submitted COPP is not valid now. Submit Original Legalised Letter of authorization as it is not submitted. Submit differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but you have submitted Rs.	

		50,000/- only. Submit Valid Copy of DSL as it is not submitted. Explain the reason on scientific grounds that why you have not performed sterility testing of applied formulation at any time point in the submitted stability studies.
	Decision: Deferred for the following: • **For submission of Stability study data of one more batch of applied formulation both accelerated & real time conducted in accordance with zone IV-A conditions as stability studies data of only two batches of applied formulation is submitted.** • **For submission of Original Legalized COPP for applied drug product as it is not valid now & Original Legalised Letter of authorization as well.** • **For submission of differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but submitted fee is Rs. 50,000/- only.** • **For Submission of Valid Copy of DSL as it is not submitted.** • **Justification/ clarification on scientific grounds for not carrying out sterility testing of applied formulation at any time point in the submitted stability studies.**	
927	Name and address of Applicant	M/s Network Marketing Services, 14C (Commercial) P.C.H.S., Defence Road, Lahore.
	Detail of Drug Sale License	Address: Validity: Status:
	Name and address of manufacturer	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu, China
	Name and address of marketing authorization holder	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu, China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 1775 Dated 12/01/2018
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Angiovision Injection
	Composition	Each ml contains: Iohexol…. 755mg (equivalent to 350mg of iodine)
	Finished Product Specification	USP Specifications
	Pharmacological Group	Water-soluble, nephrotropic, low osmolar X-ray contrast media/ Non Ionic Contrast Media
	Shelf life	24months
	Demanded Price	As per SRO
	Pack size	50ml (Iohexol 77.5g equivalent to 350mg of iodine)
	International availability	Approved in US-FDA (OMNIPAQUE 350 mg iodine/mL (755 mg of iohexol/mL)
	Me-too status	Iobrix-350 Injection Of Hoffmann Human Health Pak Ltd Lahore
	Detail of certificates attached	**<u>Original legalized COPP:</u>** Certificate No: F-2016-06001. Certified by: Jiangsu Food & Drug Administration, China. Date for Issuance: June 7, 2016. Validity: Two Years From Issuance (it is not valid now). **Free sale in exporting country:** Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to GMP as recommended by WHO as per CoPP. **<u>Original legalized GMP Certificate:</u>** Certificate No. CN20140268 Certified by: China Food & Drug Administration Date for Issuance: 05/06/2014

		Valid till**:** 05/06/2019
	Remarks of the Evaluator: Submit Valid Original legalized COPP as submitted COPP is not valid now. Submit Original Legalised Letter of authorization as it is not submitted. Submit differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but you have submitted Rs. 50,000/- only.	
	Decision: Deferred for the following: • **For submission of Original Legalized COPP for applied drug product as it is not valid now & Original Legalised Letter of authorization as well.** • **For submission of differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but submitted fee is Rs. 50,000/- only.** • **For Submission of Valid Copy of DSL as it is not submitted.**	

a. New Cases (Veterinary)

928.	Name and address of Applicant	M/s. Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of Drug Sale License	Address: Commercial Area, Aziz Bhatti Town, District Sargodha Validity: 20/11/2019 Status: Licence to sell as a "Distributer"
	Name and address of manufacturer	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.
	Name and address of marketing authorization holder	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China.
	Name of exporting country	The People's Republic Of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.24486 Dated 14/12/2017
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Enrodong -20 Oral Solution
	Composition	Each litre contains: Enrofloxacin…. 200g
	Target Species	--------
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Antibiotic
	Shelf life	24months
	Demanded Price	De-Controlled
	Pack size	1 litre
	International availability	Could not be confirmed
	Me-too status	Enroquin Forte Injection of Mehran Int Karachi
	Detail of certificates attached	**<u>LEGALIZED CERTIFICATE OF FREE SALES:</u>** **Certificate No.** No Number **Certified by:** Shandong Animal Husbandry & Veterinary Bureau. **Issued date:** 27/09/2017 **Free sale in exporting country:** Confirms the free sale of the product in exporting country. **GMP:** **<u>Legalized copy of Letter of authorization</u>** Huzaifa International & Shandong Soocom Animal remedy Co., Ltd. For following products: Oxytetracycline Injection 20 % (Oxydong-20) Enrofloxacin Oral Solution 20% (Enrodong-20) Oxytetracycline Injection 5 % (Oxydong-20) **Validity**:

Remarks of the Evaluator.

Sr. No.	Remarks of the Evaluator.	Reply of the Firm.
1	In case of finished product label, the Urdu version of Name of drug, dosage & instructions as per requirement of (Drugs labeling and prescribing rules) 1986 is required while you have not submitted the Urdu version of dosage.	Applicant has submitted Urdu version of Name of drug, dosage & instructions.
2	Submit evidence of Shandong Animal Husbandry & Veterinary Bureau as a concerned regulatory body of M/s. Shandong Soocom Animal Remedy.	-------
3	Submit stability studies both accelerated & real time of three batches of applied drug product conducted in accordance with zone IV-A conditions.	Stability of three batches of applied drug product both accelerated & real time conducted in accordance with zone IV-A condition for 24 months is submitted by the firm. (Data is same to that of 25°C ±2°C, RH 65%±5%)
4	In Assay of applied drug product it is mentioned that number of theoretical plates should be less than 2500, submit reference of this limit.	Firm has replied as follow: Chinese Veterinary Pharmaceutical Pharmacopoeia 2010 Version. Enrofloxacin test method: Enrofloxacin solution test method: Appendix page 36, HPLC test operate mehod.
5	Submit copy of valid DSL of the applicant.	Copy of DSL submitted by the firm having following information on it. **Address:** Commercial Area, Aziz Bhatti Town, District Sargodha **Validity:** 20/11/2019 **Status:** Licence to sell as a "Distributer"

Decision: Deferred for submission of complete original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data data sheets confirming conduction of stability studies of applied formulation as per Zone IVA conditions.

929.	Name and address of Applicant	Huzaifa International, Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of Drug Sale License	Address: Commercial Area, Aziz Bhatti Town, District Sargodha. Validity: 20/11/2019 Status: Licence to sell as a "Distributer"
	Name and address of manufacturer	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China
	Name and address of marketing authorization holder	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China
	Name of exporting country	The People's Republic Of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.24484 Dated 14/12/2017
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Oxydong -5 Injection
	Composition	Each 100ml contains: Oxytetracycline…. 5g
	Target Species	--------
	Finished Product Specification	Manufacturer's Specifications

Pharmacological Group	Antibiotic
Shelf life	24months
Demanded Price	De-Controlled
Pack size	100ml
International availability	Could not be confirmed
Me-too status	OXYTETRACYCLINE INJECTION of BAYER PHARMA KARACHI
Detail of certificates attached	**LEGALIZED CERTIFICATE OF FREE SALES:** Certificate No. No Number Certified by: Shandong Animal Husbandry & Veterinary Bureau. Issued date: 27/09/2017 Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP: **Legalized copy of Letter of authorization** Huzaifa International & Shandong Soocom Animal remedy Co., Ltd. For following products: Oxytetracycline Injection 20 % (Oxydong-20) Enrofloxacin Oral Solution 20% (Enrodong-20) Oxytetracycline Injection 5 % (Oxydong-5) **Validity**:

Remarks of the Evaluator.

Sr.#	Remarks of the Evaluator.	Reply of the Firm.
1	In case of finished product label, the Urdu version of Name of drug, dosage & instructions as per requirement of (Drugs labeling and prescribing rules) 1986 is required while you have not submitted the Urdu version of dosage.	Applicant has submitted Urdu version of Name of drug, dosage & instructions.
2	Submit evidence of Shandong Animal Husbandry & Veterinary Bureau as a concerned regulatory body of M/s. Shandong Soocom Animal Remedy.	-------
3	Submit stability studies both accelerated & real time of three batches of applied drug product conducted in accordance with zone IV-A conditions.	Stability of three batches of applied drug product both accelerated & real time conducted in accordance with zone IV-A condition for 24 months is submitted by the firm. (Data is same to that of 25°C ±2°C, RH 65%±5%)
4	Justification/Clarification on scientific basis for not carrying out endotoxin test of applied formulation.	According to international pharmacopoeia endotoxin test is only required to be performed for intravenous injections or powders for injections. Our applied drug product is oil based injection which is injection intramuscularly or subcutaneously, therefore endotoxin test does not require to be performed. **However applied drug product is water based injection as per data submitted in dossier.*
6	Mention the type of primary packaging material weather it is type I, Type II, Or Type III glass container.	Type I glass Container.

Decision: Deferred for submission of complete original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data data sheets confirming conduction of stability studies of applied formulation as per zone IVa conditions.

930.	Name and address of Applicant	Huzaifa International, Commercial Area, Aziz Bhatti Town,

	Sargodha.
Detail of Drug Sale License	Address: Commercial Area, Aziz Bhatti Town, District Sargodha. Validity: 20/11/2019 Status: Licence to sell as a "Distributer"
Name and address of manufacturer	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China
Name and address of marketing authorization holder	Shandong Soocom Animal Remedy co., Ltd. Xundakang Road No. 666 of Agricultural High & New Technology Development Zone of Jinan, China
Name of exporting country	The People's Republic Of China
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No.24485 Dated 14/12/2017
Fee including differential fee	Rs. 100,000/-
Brand Name +Dosage Form + Strength	Oxydong LA -20 Injection
Composition	Each 100ml contains: Oxytetracycline…. 20g
Target Species	--------
Finished Product Specification	Manufacturer's Specifications
Pharmacological Group	Antibiotic
Shelf life	24months
Demanded Price	De-Controlled
Pack size	100ml
International availability	Could not be confirmed
Me-too status	Eloxy 20% L.A Injection of Eros Pharmaceutical (Pvt) Ltd., Karachi.
Detail of certificates attached	**LEGALIZED CERTIFICATE OF FREE SALES:** Certificate No. No Number Certified by: Shandong Animal Husbandry & Veterinary Bureau. Issued date: 27/09/2017 Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP: **Legalized copy of Letter of authorization** Huzaifa International & Shandong Soocom Animal remedy Co., Ltd. For following products: Oxytetracycline Injection 20 % (Oxydong-20) Enrofloxacin Oral Solution 20% (Enrodong-20) Oxytetracycline Injection 5 % (Oxydong-5) Validity:

Remarks of the Evaluator.

Sr.#	Remarks of the Evaluator.	Reply of the Firm.
1	In case of finished product label, the Urdu version of Name of drug, dosage & instructions as per requirement of (Drugs labeling and prescribing rules) 1986 is required while you have not submitted the Urdu version of dosage.	Applicant has submitted Urdu version of Name of drug, dosage & instructions.
2	Submit evidence of Shandong Animal Husbandry & Veterinary Bureau as a concerned regulatory body of M/s. Shandong Soocom Animal Remedy.	-------
3	Submit stability studies both accelerated & real time of three batches of applied drug product conducted in accordance with zone IV-A conditions.	Stability of three batches of applied drug product both accelerated & real time conducted in accordance with zone IV-A condition for 24 months is submitted by the firm. (Data is same to that of 25°C ±2°C, RH

			65%±5%)
	4	Justification/Clarification on scientific basis for not carrying out endotoxin test of applied formulation.	According to international pharmacopoeia endotoxin test is only required to be performed for intravenous injections or powders for injections. Our applied drug product is oil based injection which is injection intramuscularly or subcutaneously, therefore endotoxin test does not require to be performed. **However applied drug product is water based injection as per data submitted in dossier.*
	6	Mention the type of primary packaging material weather it is type I, Type II, Or Type III glass container.	Type I glass Container.
	7	Submit copy of valid DSL of the applicant.	Copy of DSL submitted by the firm having following information on it. **Address:** Commercial Area, Aziz Bhatti Town, District Sargodha **Validity:** 20/11/2019 **Status:** Licence to sell as a "Distributer"
	Decision: Deferred for submission of complete original record of stability studies data both accelerated & real time for three batches supported by attested respective documents like chromatograms, laboratory reports, and raw data data sheets confirming conduction of stability studies of applied formulation as per zone IVa conditions.		

931.	Name and address of Applicant	M/s. Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No. 1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	**Address:** M/s. Ghazi Brothers, Gazi house D-35, KDA Scheme No.1. Miran Muhammad Shah Road, Karachi. **Validity:** 25 May, 2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name and address of marketing authorization holder	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.822 Dated 01/08/2016
	Fee including differential fee	Rs. 50,000/- Dated 03/01/2016
	Brand Name +Dosage Form + Strength	Sinomd Powder (for oral use)
	Composition	Each 1kg of powder contains: Bacitracin (as methylene disalicylate)… 500g (700g of bacitracin methylene disalicylate eq. to 500g of bacitracin base)
	Finished Product Specification	In House
	Pharmacological Group	Antibiotic
	Shelf life	3 years (Conditions: Accelerated 40±2, 75%±5% for 6 months Real time: 25±2, 60%±5%)
	Demanded Price	De-Controlled
	Pack size	100gm, 250gm, 500gm, 1kg, 5kg , 10kg , 25kg
	International availability	Could not be confirmed
	Me-too status	Not verified

	Detail of certificates attached	***Original Legalized Free Sale Certificate:*** • **Issued by:** Pucheng Administration of Animal Husbandry & Veterinary & Aquatic Products. • **Issued on:** 14/January/2016 • **Free sale in exporting country:** confirms the free sale of the product in exporting country. ***Original Legalized GMP Certificate:*** • **Certificate No.**: (2015) S.Y.GMP Z.Zi, No.13003 • **Issued by:** Ministry of Agriculture of the People Republic of China, Fujian Province. • **Issued on:**21/August/2015 • **Valid till:**20/August/2020 ***Original legalized letter of authorization:*** • Lifecome biochemistry Vs. Ghazi Brothers for following formulations: Sinobac 15% granular(Bacitracin 15% granular) Sinomd 15% granular (Bacitracin methylene disalicylate) Sinocol 10% granular(Colistin Sulpahte 10% granular) Sinomd water soluble (Bacitracin methylene disalicylate 50% soluble powder)
	Remarks of the Evaluator.	• Stability data is in accordance with zone IV-a Conditions.
	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.	
932.	Name and address of Applicant	M/s. Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No. 1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	**Address:** M/s. Ghazi Brothers, Gazi house d-35, KDA Scheme No.1. Miran Muhammad Shah Road, Karachi. **Validity:** 25 May, 2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name and address of marketing authorization holder	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.820 Dated 01/08/2016
	Fee including differential fee	Rs. 50,000/- Dated 13/07/2016
	Brand Name +Dosage Form + Strength	Sinocol Powder 10% (for oral use)
	Composition	Colistin as sulphate 10% granular Colistin sulphate….. 125g (as Colistin 100g)
	Finished Product Specification	In House
	Pharmacological Group	Antibiotic
	Shelf life	2 years (Conditions: Accelerated 40±2, 75%±5% for 6 months Real time: 25±2, 60%±5%)
	Demanded Price	De-Controlled
	Pack size	1kg, 5kg , 10kg , 25kg
	International availability	Could not be confirmed
	Me-too status	Not verified
	Detail of certificates attached	***Original Legalized Free Sale Certificate:*** • **Issued by:** Pucheng Administration of Animal Husbandry & Veterinary & Aquatic Products. • **Issued on:** 14/January/2016 • **Free sale in exporting country:** confirms the free sale of the product in exporting country.

		Copy of Legalized GMP Certificate: • **Certificate No.**: (2015) S.Y.GMP Z.Zi, No.13003 • **Issued by:** Ministry of Agriculture of the People Republic of China, Fujian Province. • **Issued on:**21/August/2015 • **Valid till:**20/August/2020 ***Copy of legalized letter of authorization:*** • Lifecome biochemistry Vs. Ghazi Brothers for following formulations: Sinobac 15% granular(Bacitracin 15% granular) Sinomd 15% granular (Bacitracin methylene disalicylate) Sinocol 10% granular(Colistin Sulpahte 10% granular) Sinomd water soluble (Bacitracin methylene disalicylate 50% soluble powder)
	Remarks of the Evaluator.	• Stability data is in accordance with zone IV-Conditions.
	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.	

c. Deferred Cases:

i. Human

933.	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. **Validity:** **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: 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:** Certificate No: COPP/CERT/KD/60727/2017/11/20552/103919 Certified by: Food & Drug administration, M.S. Bandra-Kurla Complex Bandra –Kurla Complex, Mumbai, Maharashtra State, India Issued on: 23/08/2017 Valid up to: 17th May 2019

		Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP**:**The facilities and operations conform to GMP as recommended by WHO as per CoPP. **<u>Original legalized Free sale Certificate:</u>** (This certificate is issued for export registration) Certificate No: 6078190 Certified by: Food & Drugs Administration Konkan Division, Maharashtra State, India. Issued date: 24/10/2017 Validity: Untill 23/10/2018
	Remarks of the Evaluator.	• Reliance Life sciences has submitted two Original legalized Free sale Certificate as mentioned below: One certificate is issued for export registration only.(In-House) Second certificate is issued for product freely sold in India(IP) • 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.
	Previous decision	Registration Board in its 288th meeting deferred the case for the following: For submission of stability data at real time of three batches of applied formulation as per Zone IVa till claimed shelf life.
	Evaluation by PEC	Applicant has submitted stability studies.
	Decision: Approved with innovator's specification & as per Policy for inspection of Manufacturer abroad.	
934.	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. **Validity:** **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: 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	**<u>Original legalized CoPP:</u>**

		Certificate No: COPP/CERT/KD/60572/2017/11/20441/103630 Certified by: Food & Drug administration, M.S. Bandra-Kurla Complex Bandra –Kurla Complex, Mumbai, Maharashtra State, India Issued on: 11/08/2017 Valid up to: 17th May 2019 Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP**:**The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Original legalized Free sale Certificate:** (This certificate is issued for export registration) Certificate No: 6078191 Certified by: Food & Drugs Administration Konkan Division, Maharashtra State, India. Issued date: 24/10/2017 Validity: Untill 23/10/2018
	Remarks of the Evaluator.	• Reliance Life sciences has submitted two Original legalized Free sale Certificate described below: One certificate is issued for export registration only.(In-House) Second certificate is issued for product freely sold in India(IP) • Data of 03 batches supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.
	Previous decision	Registration Board in its 288th meeting deferred the case for the following: For submission of stability data at real time of three batches of applied formulation as per Zone IVa till claimed shelf life.
	Evaluation by PEC	Applicant has submitted stability studies.
	Decision: Approved with innovator's specification & as per Policy for inspection of Manufacturer abroad.	

ii. Veterinary.

935.	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. Validity: 11/02/2019 Status: Licence to sell as a "Distributer"
	Name and address of manufacturer	M/s Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia.
	Name and address of marketing authorization holder	M/s Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia.
	Name of exporting country	Malaysia
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.26359 Dated 28/12/2017
	Fee including differential fee	Rs. 100,000/- Dated 23/12/2017
	Brand Name +Dosage Form + Strength	Quinosol 20% Solution (oral) (Water Soluble Liquid: Enrofloxacin; 200mg/ml)
	Composition	Each 1ml of liquid contains: Enrofloxacin ……. 200mg
	Target Species	Broilers, Turkeys, Pullets
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Antibiotic

Shelf life	36 months
Demanded Price	De-Controlled
Pack size	200ml, 500ml, 1liter
International availability	
Me-too status	Enroxsel 20 Oral Solution Of Selmore Pharmaceuticals
Detail of certificates attached	**Original legalized CoPP** **Certificate No. 0473H/2017** **Certified by:** Drug Control Authority, National Pharmaceutical Regulatory Division (NPRA), Ministry Of Health Malaysia. **Issued date:** 27/09/2017 **Free sale in exporting country:** Confirms the free sale of the product in exporting country. **GMP:** The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Letter of authorization** Vet line international & Range Pharma **Validity**: 3years from date of signature i.e. 15th-05-2017.
Remarks of the Evaluator.	• Quantity of excipients mentioned in product formula attached alongside the COPP is different from that mentioned in SmPC & under Heading of composition on Form 5A. Clarify/Justify. • Justification on scientific basis for addition of 2 % overage of enrofloxacin in master formulation. • Long term stability data of API is for Neomycin Sulphate instead of Enrofloxacin. • In Finished Product Specifications under microbial contamination test, limits of microbial count are not mentioned. Mention the limits of microbial count.
Previous Decision	Registration Board in its 287th meeting deferred the case for the following: • Quantity of excipients mentioned in product formula attached alongside the COPP is different from that mentioned in SmPC & under Heading of composition on Form 5A. Clarify/Justify. • Justification on scientific basis for addition of 2 % overage of enrofloxacin in master formulation. • Long term stability data of API is for Neomycin Sulphate instead of Enrofloxacin. • In Finished Product Specifications under microbial contamination test, limits of microbial count are not mentioned. Mention the limits of microbial count.

Evaluation by PEC:

Sr. No.	Registration Board in its 287th meeting deferred the case for the following reason:	Response of the firm
1	• Quantity of excipients mentioned in product formula attached alongside the COPP is different from that mentioned in SmPC & under Heading of composition on Form 5A. Clarify/Justify.	The firm has submitted a clarification letter from M/s. Range Pharmaceuticals addressed to DRAP wherein it is stated that in the COPP, the amount of active ingredient, enrofloxacin, is expressed per ml (200mg/ml) whilst the excipients are expressed per litre (L). Whereas both the active ingredient & excipients mentioned in the SmPC & composition provided under form 5A were expressed per ml. The COPP unit description is due to the way the product content is recorded in our Registration filling with our Regulatory Body. However, we confirm that the attached COPP, SmPc, & Composition provided under heading of

			composition on form 5A are equivalent, which are as follow: Each ml of Quinosol 20% solution contains: Active substance: Enrofloxacin… 200mg Excipients: Potassium hydroxide… 32mg Propylene glycol…200mg Sodiumthiosulfite…1.25gm Benzyl alcohol… 0.01ml Purified water… 0.05ml
	2	Justification on scientific basis for addition of 2 % overage of enrofloxacin in master formulation.	The additional 2% overage of enrofloxacin in master formulation is added to compensate the processing or handling loss during production.
	3	Long term stability data of API is for Neomycin Sulphate instead of Enrofloxacin.	Long term stability data of API (Enrofloxacin.) is submitted.
	4	In Finished Product Specifications under microbial contamination test, limits of microbial count are not mentioned. Mention the limits of microbial count.	Firm has submitted that microbial contamination test limits were established according to BP 2012 (Appendix XVID, Microbiological Quality of Non-sterile Pharmaceutical Preparations & Substance for Pharmaceutical use.)
	Decision: Approved with innovator's specification.		
936.	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. Validity: 11/02/2019 Status: Licence to sell as a "Distributer"	
	Name and address of manufacturer	M/s Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia.	
	Name and address of marketing authorization holder	M/s Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia.	
	Name of exporting country	Malaysia	
	Type of Form	Form 5-A	
	Diary No. & Date of R& I	Dy. No.26358 Dated 28/12/2017	
	Fee including differential fee	Rs. 100,000/-	
	Brand Name +Dosage Form + Strength	Mucolin 1% Powder(Oral) (Water Soluble Liquid: Bromhexine hydrochloride; 10mg/ml)	
	Composition	Each 1ml of liquid contains: Bromhexine hydrochloride ……. 10mg	
	Target Species	Cattle, Poultry	
	Finished Product Specification	Manufacturer's Specifications	
	Pharmacological Group	Mucolytic	
	Shelf life	36 months	
	Demanded Price	De-Controlled	
	Pack size	200ml, 500ml, 1liter	
	International availability		
	Me-too status	Broncoden of Lexicon & broncoveex of Samara	
	Detail of certificates attached	**Original legalized CoPP** **Certificate No. 0479H/2017** **Certified by:** Drug Control Authority, National Pharmaceutical Regulatory Division (NPRA), Ministry Of Health Malaysia. **Issued date:** 25th /09/2017	

		Free sale in exporting country: Confirms the free sale of the product in exporting country. **GMP:** The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Letter of authorization** Vet line international & Range Pharma **Validity**: 3years from date of signature i.e. 15th-05-2017.
	Remarks of the Evaluator.	• Justification on scientific basis for addition of 2 % overage of Bromhexine hydrochloride in master formulation. • In Finished Product Specifications under microbial contamination test, limits of microbial count are not mentioned. Mention the limits of microbial count. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as the provided me too contains some other ingredients as well.
	Previous Decision	Registration Board in its 287th meeting deferred the case for the following: • Justification on scientific basis for addition of 2 % overage of Bromhexine hydrochloride in master formulation. • In Finished Product Specifications under microbial contamination test, limits of microbial count are not mentioned. Mention the limits of microbial count. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as the provided me too contains some other ingredients as well.

Evaluation by PEC

Sr. No.	Registration Board in its 287th meeting deferred the case for the following reason:	Response of the firm
1	Justification on scientific basis for addition of 2 % overage of Bromhexine hydrochloride in master formulation.	The additional 2% overage of enrofloxacin in master formulation is added to compensate the processing or handling loss during production.
2	In Finished Product Specifications under microbial contamination test, limits of microbial count are not mentioned. Mention the limits of microbial count.	Firm has submitted that microbial contamination test limits were established according to BP 2012 (Appendix XVID, Microbiological Quality of Non-sterile Pharmaceutical Preparations & Substance for Pharmaceutical use.)
3	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as the provided me too contains some other ingredients as well	Evidence of Me TOO Brand Name: Bromocin Oral Liquid Name of manufacturer: Biogen Pharma Registration NO: 063803

Decision: Approved with innovator's specification.

937.	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. **Validity:** 11/02/2019 **Status:** Licence to sell as a "Distributer"
	Name and address of manufacturer	M/s Bela Pharm GmbH & Co.KG LohnerStrasse 19

		49377 Vechta, Germany.
	Name and address of marketing authorization holder	M/s Bela Pharm GmbH & Co.KG LohnerStrasse 19 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: Neomycin Sulphate……. 1000mg
	Target Species	Cattle, Chicken
	Finished Product Specification	Manufacturer's Specifications
	Pharmacological Group	Aminoglycoside antibiotic
	Shelf life	2years
	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** **Certificate No. 41401-7/8-14/012** **Certified by:** Staatl. Gewerbeaufsichtsamt Oldenburg, Theodor- Tantzen- Platz 8 D-26122 Oldenburg. **Issued date:** 03/04/2014 **Free sale in exporting country:** Confirms the free sale of the product in exporting country. **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. • Submit Original legalized COPP as you have submitted Copy of COPP. *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.*
	Previous Decision	Registration Board in its 288th Meeting deferred the case for the following: • Submission of original, legalized and Valid CoPP. • Submision of Long term stability studies conducted under the conditions of zone IV-A of remaining 1 batch till shelf life.
	Evaluation by PEC	

Sr.	Registration Board in its 288th	Response of the firm

	No.	Meeting deferred the case for the following:	
	1	Submission of original, legalized and Valid COPP.	Applicant has submitted the following: **Original legalized CoPP** **Certificate No. DE-NI-04-WHO-2019-0008** **Certified by:** Staatl. Gewerbeaufsichtsamt Oldenburg, Theodor- Tantzen- Platz 8 D-26122 Oldenburg. **Issued date:** 11/02/2018 **Free sale in exporting country:** Confirms the free sale of the product in exporting country. **GMP:** The facilities and operations conform to GMP as recommended by WHO as per COPP.
	2	Submission of Long term stability studies conducted under the conditions of zone IV-A of remaining 1 batch till shelf life.	Applicant has submitted stability study data both accelerated & real time for one more batch of applied drug product.
	Decision: Approved with innovator's specification.		

Case no. 07 Registration applications of drugs for which stability study data is submitted.

a. Verification of stability study data

938.	Name and address of manufacturer / Applicant	M/s Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E., Karachi- 75700
	Brand Name +Dosage Form + Strength	Apixa tablet 5mg
	Composition	Each film coated tablet Contains: Apixaban …. 5mg
	Diary No. Date of R& I & fee	Dy. No. 21690: 21-06-18, 20,000(23-12-14)+30,000(17-05-16) duplicate fee challan
	Pharmacological Group	Antithrombotic Agents
	Type of Form	Form-5D
	Finished product Specifications	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 (with strength and dosage form)	N/A
	GMP status	--------

STABILITY STUDY DATA			
Drug	Apixa tablet 5mg		
Name of Manufacturer	M/s Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E., Karachi- 75700		
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., LTD. Previously (M/s. Jiangxi Tonghe Pharmaceutical Co., Ltd.)		
API Lot No.	20170204V		
Description of Pack (Container closure system)	14's: Alu/PVC blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Accelerated: 3 Month	Real Time: 3 Month	
Frequency	Accelerated: 0,3,6 (Month)	Real Time: 0,3,6 (Month)	
Batch No.	17PD067APIT01(A)	17PD067APIT01(B)	17PD083APIT02(A)

Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	October 2017	October 2017	November 2017
Date of Initiation	04-12-2017	04-12-2017	15-01-2018
No. of Batches	03		
Date of Submission	21-06-2018 (Dy. No. 21690)		

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.	M/s Jiangxi Synergy Pharmaceutical Co., LTD. This was Previously named as M/s. Jiangxi Tonghe Pharmaceutical Co., Ltd. (As per API manufacture's Web information). **Certificate number** : JX20150013 **Validity**: 05-03-2020
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.	Yes ADC attested commercial invoice of August, 2017 stating 0.2 kg of apixaban is submitted by the firm
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

939.	Name and address of manufacturer / Applicant	M/s Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E., Karachi- 75700
	Brand Name + Dosage Form + Strength	Apixa tablet 2.5mg
	Composition	Each film coated tablet Contains: Apixaban …. 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 21690: 21-06-18, 20,000(23-12-14)+30,000(17-05-16) duplicate fee challan
	Pharmacological Group	Antithrombotic Agents
	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 US-FDA
	Me-too status (with strength and dosage form)	N/A
	GMP status	--------

STABILITY STUDY DATA

Drug	Apixa tablet 2.5mg
Name of Manufacturer	M/s Pharmatec Pakistan (Private) Limited, D-86/A, S.I.T.E., Karachi- 75700
Manufacturer of API	M/s Jiangxi Synergy Pharmaceutical Co., LTD.

	Previously (M/s. Jiangxi Tonghe Pharmaceutical Co., Ltd.)		
API Lot No.	20170204V		
Description of Pack (Container closure system)	10's: Alu/PVC blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Accelerated: 3 Month Real Time: 3 Month (Now they have submitted six month data of both real time and accelerated)		
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	17PD066APIT01(A)	17PD066APIT01(A)	17PD092APIT04(A)
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	October 2017	October 2017	November 2017
Date of Initiation	30-11-2017	04-12-2017	15-01-2018
No. of Batches	03		
Date of Submission	21-06-2018 (Dy. No. 21690)		

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.	M/s Jiangxi Synergy Pharmaceutical Co., LTD. This was Previously named as M/s. Jiangxi Tonghe Pharmaceutical Co., Ltd. (As per API manufacture's Web information). **Certificate number** : JX20150013 **Validity**: 05-03-2020
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.	Yes ADC attested commercial invoice of August, 2017 stating 0.2 kg of Apixaban is submitted by the firm
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

Inspection Report

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Apixa 2.5mg & 5mg (Apixaban) Tablets by M/s. Pharmatec Pakistan (Private) Ltd., S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 23rd January, 2019.
Investigation Date and Time: 30th April, 2019 (Morning).

Investigation Site: Factory premises of M/S. Pharmatec Pakistan (Private) Ltd., D-86/A, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/S. Pharmatec Pakistan (Private) Ltd., D-86/A, S.I.T.E, Karachi for registration of Apixa 2.5mg & 5mg (Apixaban) 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. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Women, Karachi. (Member Registration Board) Islamabad.
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Mr. Abdul Waheed, 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:

APIXA 2.5MG AND 5MG TABLETS

Sr.#	Question	Observation bypanel
1.	Doyouhavedocumentsconfirmingthe import of Apixaban API including approvalfromDRAP?	Thefirmhasimported 0.2 kg Apixaban API (Lot No. 20170204V) fromM/S. Jiangxi Synergy Pharmaceutical Co., Ltd., China. Approval fromDRAP Office,Karachi was obtained on August, 2017.
2.	Whatwastherationalebehind selecting the particularmanufacturer ofAPI?	There is proper vendor evaluation process being implementedincluding auditchecklist,Testingof the APIand GMP approvalbycompetentauthority along with the DMF.
3.	Doyouhavedocumentsconfirmingthe importof Apixaban reference standard and impuritystandard?	The firm has document confirming the import of Apixaban (API), working standardoftheAPIand 8 major impuritiesfromthe manufacturerofthe API.
4.	Do you have certificate of Analysis of the API,referencestandardoftheAPIand impuritystandard?	ThefirmhascertificateofanalysisfortheAPI,working standardofthe API and 8 impurities standards.
5.	Do youhaveGMPcertificateofAPI manufacturers issued by regulatory authoritiesofcountryoforigin?	The firm has valid GMP certificate of the API manufacturer issued by the concerned provincial Regulatory Authority of thecountryoforigin.
6.	DoyouuseAPImanufacturermethodof testingfortestingAPI?	Thefirmhasused API manufacturer methodfor testing API.
7.	Doyouhavestabilitystudiesreporton API?	The firmhasstabilitystudies reports on the API.
8.	Ifyes,whetherthestabilitytestinghas beenperformedasperSIM methodand degradation products have been quantified?	The stabilitytestinghasbeen performed as per SIM method and major degradationproducts (02) have been quantified.
9.	Doyouhavemethodforquantifyingthe impuritiesinthe API?	The firmhasmethodforquantifying the impurities in the API.
10.	Doyouhavesomeremainingquantitiesof the API, its reference standard and impuritiesstandards?	ThefirmhasremainingquantitiesoftheAPI, working standard of API and 08 impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients including Avicell PH 102, Povidone, Talc, Magnesium Stearate, Opadry.

12.	Doyouhavedocumentsconfirmingthe importoftheusedexcipients?	The firm has documents confirming the import of all excipients used.
13.	Doyouhavetestreportsandotherrecords on theexcipients used?	The firmhastest reports and other records on the excipient used.
14.	Do you have written and authorized protocols for thedevelopmentof Apixa Tablets?	The firmhas written and authorized protocols for the developmentof Apixa 2.5mg and 5mg Tablets.
15.	Have you performed Drug-excipient compatibilitystudies?	Drug excipients compatibility testing has not been performed as formulations are same as that of innovator tablets.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies of 2.5mg and 5mg Apixa tablets against innovator tablets (Eliquis 2.5mg and 5mg tablets manufactured by BMS, USA) and their tablets have shown comparable dissolution profiles to that of the innovator tablets.
17.	Doyouhaveproductdevelopmentsection?	The firm has product development section with equipment for manufacturing of tablet dosage form. The analytical part has been performed in routine QC Lab. The R&D section needs improvements in terms of segregation of operations and HVAC system.
18.	Do you have necessary equipment availableinproduct developmentsection fordevelopmentof Apixa Tablets?	As above.
19.	Arethe equipment in product developmentsection qualified?	The available equipment in product development section are qualified.
20.	Do you have proper maintenance calibration / re-qualificationprogramfor the equipmentusedin PD section?	The firm has proper maintenance/ calibration withre-qualificationprogramfor the equipment used for product development.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has a team of 04 technicalpersons (03 Pharmacist & 1 Chemist) for product development. These personnel have proper knowledge and training in product development.
22.	Have you manufactured three stability batches for the stability studies of Apixa tablets asrequired?	The firm has manufactured three stability batches of: 1. Apixa Tablets 2.5mg havingbatch # 17PD066APIT01(A), 17PD066APIT01(A) and 17PD092APIT04 (A) eachof5000 tablets batchsize. 2. Apixa Tablets 5mg havingbatch # 17PD067APIT01(A), 17PD067APIT01(B) and 17PD083APIT02 (A) eachof5000 tablets batchsize. The tablets are packed in Alu/PVC blisters ofpacksize 14's and 10's for 5mg & 2.5mg strengths respectively.
23.	Doyouhaveanycriteriaforfixingthe batchsize ofstabilitybatches?	The criteria for fixing the batch size of stability batches is the equipment size (Maximum 5kg) of tablets and the number of tablets required for whole stability testing.
24.	Do you have complete record of production ofstabilitybatches?	The firm hascompleterecordofproductionofstability batches. Allthe LogBooks are properly maintained.
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 used the API related substance method for testing of their stability batches. The stability indicating nature of the method has been supported by forced degradation studies. Spiking studies also have been performed recently. The method is also completely validated.
27.	Doyouhavemethodtransferstudiesin casewhenthemethodoftestingbeing usedbyyourfirmisgivenbyanyother lab?	The firm has performed complete validation studies.

28.	Doyouhavedocumentsconfirmingthe qualificationofequipments/instruments being used in the test and analysis of Apixaban APIand the finished drug?	The firm has proper documents confirming the qualificationofequipment/instrumentsbeingusedinthe testandanalysis ofthe APIand the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of analysis is stability indicating.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm and as evidenced by the practices.
31.	Can you show Audit trail reports on Apixaban testing?	Audittrailonthetestingreports is available.
32.	Do you have some remaining quantitiesof degradation products and stability batches?	Thefirmhasremainingquantitiesof two degradation products (major degradation products) and stability batches.
33.	Do you have stability batches kept on stabilitytesting?	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. Degradation products quantification has been made on 12 months studies, however, testing has been performed throughout as per SIM method.
34.	Doyouhavevalidcalibrationstatus for the equipment's used in Apixa Tablets production andanalysis?	Thefirmhasvalidcalibrationstatusfortheequipmentused in Apixa 2.5mg and 5mg 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 berated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities are 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 Apixa 2.5mg and 5mg (Apixaban) Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Apixa 2.5mg and 5mg (Apixaban) Tablets.

Recommendations:

1. Apixa 2.5mg and 5mg (Apixaban) Tablets are recommended for registration in the name of the firm.
2. The API falls in BCS Class III (Highly soluble and Poorly permeable) and has problematic bioavailability and the reference product (EMA Assessment Report on Eliquis Tablet) has shown significant variation (20%-30%) within participants, therefore, the panel recommends post-registration bioequivalence studies and post-marketing safety studies on Apixa tablets also.

Decision: Registration Board decided to approve registration of "Apixa 2.5mg and 5mg (Apixaban) Tablets by M/S. Pharmatec Pakistan (Private) Ltd. 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.

940.	Name and address of manufacturer / Applicant	M/s Getz Pharma (Pvt.) Ltd. 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	EstineTablets 10mg
	Composition	Each Oro-dispersible tablet contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy.No. 4910; 06-06-17: Rs. 20,000 & Rs. 30,000
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's: Rs. 250.00/-
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM
	Me-too status (with strength and	N/A

	dosage form)	
	GMP status	Based on the area inspected, the people met and the documents reviewed, the considering the findings of the inspection, including the observations listed in the inspection report, M/s Getz Pharma, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today.

STABILITY STUDY DATA

Drug	EstineTablets 10mg (Ebastine10mg)		
Name of Manufacturer	M/s Getz Pharma (Pvt.) Ltd. 29-30/27, Korangi Industrial Area, Karachi.		
Manufacturer of API	Bal Pharma Limited, India		
API Lot No.	API Batch # 500111706023		
Description of Pack (Container closure system)	Alu-Alu blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 06 Months Accelerated:06Months		
Frequency	Real Time: 0,3,6 Months(on going) Accelerated: 0,3,6 Months		
Batch No.	418DS01	418DS02	418DS03
Batch Size	25000 tablets	25000 tablets	25000 tablets
Manufacturing Date	January, 2018	January, 2018	January, 2018
Date of Initiation	March, 2018	March, 2018	March, 2018
No. of Batches	03		
Date of Submission	Dy. No.38888, 27-11-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	COA of Ebastine from Bal Pharma Limited, 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**: **Certificate No**. DCD/CR-2096 GSC NO. 13561/SPL.CL-I/2017-2018. **Issued By:** Drugs Control Department, Government of Karnataka. **Validity:** One year from date of Issue i.e. 05th April 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.	
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of	Yes

	data / documents.	
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Inspection Report

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Estine (Ebastine) 10mg & 20mg Oro-dispersible Tablets by M/s Getz Pharma Pvt. Limited, 29-30/27, Korangi Industrial Area , Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 25th April, 2019.
Investigation Date and Time: 6th May, 2019. (Forenoon)
Investigation Site: Factory premises of M/s Getz Pharma Pvt. Limited, 29-30/27, Korangi Industrial Area, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Getz Pharma Pvt. Limited, 29-30/27, Korangi Industrial Area, Karachi for registration of Estine (Ebastine) 10mg & 20mg Oro-dispersible 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, Dean Faculty of Pharmacy, Ziauddin University. (Member Registration Board)
2. Dr. Kirshan Das, Assistant Director, 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:
Estine (Ebastine) Tablets 10mg & 20mg, Oro-dispersible Tablets

Q. No.	Question	Observation by panel
1	Do you have documents confirming the import of Ebastine API including approval from DRAP?	The firm has imported "Ebastine API" from M/s Bal Pharma Ltd, India and has approval from DRAP for import vide License No.1657/17-DRAP (K) dated 21.06.2017.
2	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through Postal Audit checklist / Physical Site Inspection and availability of valid GMP approval by competent authority. Further, M/s Bal Pharma Ltd, India has Certificate of Suitability (CEP) for Ebastine API issued by European Directorate for the Quality of Medicines & HealthCare (EDQM).
3	Do you have documents confirming the import of Ebastine reference standard and	Firm has imported Ebastine working standard from M/s Bal Pharma Ltd, India vide invoice No. SAM-010 dated

	impurity standards?	14.06.2017. For impurity testing, firm has used Relative Retention Time (RRT) for location and calculation of impurities as provided by Ph. Eur.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificate of analysis for API and working standard.
5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has provided copy of valid GMP certificate of M/s Bal Pharma Ltd, India valid till 04-02-2020.
6	Do you use API manufacturer method of testing for testing API?	The firm has used method of testing adopted from European Pharmacopeia (Ph. Eur) monograph for Ebastine API and the same has been verified as per USP chapter 1226 (verification of compendial procedure)
7	Do you have stability studies reports on API?	The firm has 5 years real time stability study data provided by API manufacturer.
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?	Yes, the firm has method for quantifying the impurities in the API adopted from European Pharmacopeia (Ph. Eur) monograph for Ebastine API.
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of the API and working standard.
11	Have you used pharmaceutical grade excipients?	The firm have used pharmaceutical grade excipients which include Microcrystalline Cellulose (Avicel PH-101), Mannitol, Poloxamer 188, Povidone K-30, Hypromellose, Carboxymethylcellulose Calcium, Colloidal Anhydrous Silica, Croscarmellose Sodium, Crospovidone, Aspartame, Trusil Powder Orange Flavour and Magnesium Stearate.
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 Ebastine tablets?	The firm has written and authorized protocols for the development of Ebastine Oro-dispersible Tablets 10mg & 20mg.
15	Have you performed Drug-excipient compatibility studies?	The firm has performed Drug-excipient compatibility studies and concluded that the excipients used in the proposed formulation of Ebastine Oro-dispersible Tablets 10mg & 20mg are compatible with the API.
16	Have you performed comparative dissolution studies?	The firm has used dissolution criteria as per Japanese Pharmacopoeia monograph for Ebastine Oro-dispersible Tablets and the product complies. Further, this product is orally dispersible which disintegrates very rapidly. The release is more than 85% within 15 minutes, therefore, F2 waiver is applicable.
17	Do you have product development (R&D) section	The firm has dedicated product development (R&D) section with requisite manufacturing and analysis facilities.
18	Do you have necessary equipment available in product development section for development of Ebastine tablets?	The firm has necessary equipment available in product development section for development ofEbastine Oro-dispersible Tablets 10mg & 20mg.
19	Are the equipment in product development section qualified?	The available equipment in product development section are qualified.

<table>
<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 proper maintenance / calibration with re-qualification program for the equipment used in 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 in product development section with proper knowledge and training in product development. There are 50 Scientists (Pharmacist & Chemist) working only in R&D Section.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Ebastine tablets as required?</td><td>The firm has manufactured three stability batches of Ebastine Oro-dispersible Tablets 10mg & 20mg. Packed in Alu-Alu blisters:
<table>
<tr><td colspan="3">Ebastine Tablets 10mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>418DS01</td><td>January 2018</td><td>2500 Tablets</td></tr>
<tr><td>418DS02</td><td>January 2018</td><td>2500 Tablets</td></tr>
<tr><td>418DS03</td><td>February 2018</td><td>2500 Tablets</td></tr>
</table>
<table>
<tr><td colspan="3">Ebastine Tablets 20mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>419DS01</td><td>January 2018</td><td>4000 Tablets</td></tr>
<tr><td>419DS03</td><td>February 2018</td><td>4000 Tablets</td></tr>
<tr><td>419DS04</td><td>March 2018</td><td>4000 Tablets</td></tr>
</table></td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the capacity of their R&D equipment where probable simulation of manufacturing procedure of production batches are expected as well as quantity of tablets 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 complete record of production of stability batches. All the Log Books are properly maintained.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocols for stability testing of stability batches having protocol number:
<table>
<tr><td colspan="2">Ebastine Tablets 10mg</td></tr>
<tr><td>Batch No.</td><td>Protocol No.</td></tr>
<tr><td>418DS01</td><td>FS-019-18</td></tr>
<tr><td>418DS02</td><td>FS-020-18</td></tr>
<tr><td>418DS03</td><td>FS-021-18</td></tr>
</table>
<table>
<tr><td colspan="2">Ebastine Tablets 20mg</td></tr>
<tr><td>Batch No.</td><td>Protocol No.</td></tr>
<tr><td>419DS01</td><td>FS-022-18</td></tr>
<tr><td>419DS03</td><td>FS-023-18</td></tr>
<tr><td>419DS04</td><td>FS-024-18</td></tr>
</table></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 the method for testing of stability batches.</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 given by any other lab?</td><td>The firm has developed and validated method of testing for finished product and complete Method Validation Report is available. Therefore, method transfer is not applicable.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Ebastine API and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Ebastine API and the finished drug.</td></tr>
<tr><td>29</td><td>Do your method of analysis stability indicating?</td><td>The firm has performed forced degradation (FD) study on their product Ebastine Oro-dispersible Tablets 10mg & 20mg for the conformance of its stability indicating nature.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software is 21CFR Compliant as per record</td></tr>
</table>

		available with the firm. The firm have WATER's HPLC with Empower 3 software having following features: • Have Audit trail • Have backup system • Have Data traceability • Have Data achieving system • Have data integrity • Have Data security System Security Policy
31	Can you show Audit trail reports on Ebastine testing?	Audit trail on the testing reports is available.
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 stability batches kept on stability testing?	The firm has three stability batches kept on real time stability testing. 12 months real time stability data is available.
34	Do you have valid calibration status for the equipments used in Ebastine tablets production and analysis?	The firm has valid calibration status for the equipment used in production and analysis of Ebastine Oro-dispersible Tablets 10mg & 20mg.
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 having alarm system for alerts as well.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Estine (Ebastine) 10mg & 20mg Oro-dispersible 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 Estine 10mg & 20mg Oro-dispersible Tablets.

Recommendations:

The firm may kindly be granted necessary registration of Estine 10mg & 20mg Oro-dispersible tablets.

Decision: Registration Board decided to approve registration of "Ebastine tablets 10 mg by M/s Getz Pharma (Pvt) Ltd., Karachi, with the change in brand name. 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.

941.	Name and address of manufacturer / Applicant	M/s Dyson research laboratories 28 km, Ferozepur Road Lahore.
	Brand Name +Dosage Form + Strength	Dexal Capsule 30mg
	Composition	Each capsule contains: Dexlansoprazole…30mg
	Diary No. Date of R& I & fee	Dy No. 143; 13-01-16 : Rs. 50,000/- (23-12-15)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's: Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	N/A
	GMP status	

STABILITY STUDY DATA

Drug	Dexal Capsule 30mg (Dexlansoprazole…30mg)		
Name of Manufacturer	M/s Dyson research laboratories 28 km, Ferozepur Road Lahore.		
Manufacturer of API	M/s Spansules Formulation, India		
API Lot No.	Dexlansoperazole DDR pellets 17.0% w/w. (Batch. # DLT/SF/0010117)		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 09 Months Accelerated:06Months		
Frequency	Real Time: 0,1,3,6,9 Months(on going) Accelerated: 0,1,3,6 Months		
Batch No.	T01	T02	T03
Batch Size	2200 Capsules	2200 Capsules	2200 Capsules
Manufacturing Date	03-2017	03-2017	03-2017
Date of Initiation	03-2017	03-2017	03-2017
No. of Batches	03		
Date of Submission	Dy No.27052(07-08-18)		

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 applicant has submitted the following documents: **GMP Certificate:** **Issued to**: M/s Spansules Formulations, India. **Issued on**: 05-09-2018 **Issued by**: Drug Control Administration, Telangana, India. **Validity**: One year from the date of Issue.
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.	Applicant has submitted following: Letter of Permission to import API signed by AD (I&E) Lahore on 19-12-16. Copy of commercial invoice for Dexlansoperazole pellets 17%., attested by AD (I&E), DRAP Lahore on 03-02-2017 3.983 kgs.
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		
942.	Name and address of manufacturer / Applicant	M/s Dyson research laboratories 28 km, Ferozepur Road Lahore.
	Brand Name +Dosage Form + Strength	Dexal Capsule 60mg
	Composition	Each capsule contains: Dexlansoprazole…60mg
	Diary No. Date of R& I & fee	Dy No. 144; 13-01-16 : Rs. 50,000/- (25-12-15)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's: Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	N/A
	GMP status	

STABILITY STUDY DATA			
Drug	Dexal Capsule 60mg (Dexlansoprazole 60mg)		
Name of Manufacturer	M/s Dyson research laboratories 28 km, Ferozepur Road Lahore.		
Manufacturer of API	M/s Spansules Formulation, India		
API Lot No.	Dexlansoperazole DDR pellets 17.0% w/w. (Batch. # DLT/SF/0010117)		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Real Time: 09 Months Accelerated:06Months		
Frequency	Real Time: 0,1,3,6,9 Months(on going) Accelerated: 0,1,3,6 Months		
Batch No.	T01	T02	T03
Batch Size	2200 Capsules	2200 Capsules	2200 Capsules
Manufacturing Date	03-2017	03-2017	03-2017
Date of Initiation	03-2017	03-2017	03-2017
No. of Batches	03		
Date of Submission	Dy No.27053, 07-08-18		

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 applicant has submitted the following documents: **GMP Certificate:** **Issued to**: M/s Spansules Formulations, India. **Issued on**: 05-09-2018 **Issued by**: Drug Control Administration, Telangana, India. **Validity**: One year from the date of Issue.
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.	Applicant has submitted following: Letter of Permission to import API signed by AD (I&E) Lahore on 19-12-16. Copy of commercial invoice for Dexlansoperazole pellets 17%., attested by AD (I&E), DRAP Lahore on 03-02-2017 for 3.983 kgs.
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
Queries & Response of the firm		
Sr. No.	**Queries**	**Response of firm & its Evaluation by PEC**
1.	Submit Approval of API/DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin as only Copy of DML has been submitted by the firm.	The applicant has submitted the following documents: ***GMP Certificate****:* ***Issued to:*** *M/s Spansules Formulations, India.* ***Issued on****: 05-09-2018* ***Issued by:*** *Drug Control Administration, Telangana, India.* ***Validity:*** *One year from the date of Issue.*
2.	API & working standards were purchased from M/s Spansules Formulations & Impurity standard from Everest organics limited is used, Clarify/Justify.	In response to this query applicant has submitted a statement by M/s Spansules Formulations which is stated below: *With reference to our supply of Dexlansoperazole DDR pellets to our customer M/s Dyson Research Laboratories (Pvt) for their trial & stability studies, we confirm that we are pellets manufacturer & we purchase API Powder for pellets manufacturing from Indian manufacturer M/s Everest Organic Ltd.* *Hence our customer purchased impurities directly from Everest Organics Ltd. On our recommendation.*
3.	You have submitted COA for Dexlansoperazole DDR pellets 17.0% w/w in which the manufacturer of API did not performed impurity profiling of pellets. Clarify/Justify.	In response to this query applicant has submitted a statement by M/s Spansules Formulations which is stated below: *With reference to our supply of Dexlansoperazole DDR pellets to our customer M/s Dyson Research Laboratories (Pvt) for their trial & stability studies, we confirm that we are pellets manufacturer in india & pellets are ready to fill product made with the mixing with several inactives so impurity profile cannot be tested in biproduct. Since we have conducted stability studies of pellets of Dexlansoprazole, impurities profile was not required.*
4.	Batch numbers of trial batches for applied drug product i.e. Dexal Capsule 30mg is T01, T02, T03 which is same to that of Dexal Capsule	The Applicant has submitted its clarification: We are using "T"-series for our trial batches only, in which numerical figures represents n = number of trials

	60mg i.e. T01, T02, T03. Justify/Clarify how the firm has distinguished between trial batches of two strength of applied drug product.	conducted (i.e. n= 1, 2, 3, 4, 5….). Furthermore, products can be identified against their strengths as Dexal capsule 30mg & 60mg respectively & labelling for trail packs done accordingly to distinguish between same products having different strengths.
5.	Dissolution test at first month studies of all three trial batches of Dexal capsule 30mg & Dexal capsule 60mg is not performed, Clarify.	The applicant has submitted the following justification: *Dissolution test for trial batches T01, T02, T03,was not performed for Ist month only, while all other tests including Assay were performed & were with Specified limits. So you are requested to consider our stability data for other months for evaluation. Since the dissolution results of 0, 3 & 6 months (as per ICH guidelines) comply with specifications; product anyhow is stable as per reports of stability.* However, dissolution test at 3rd month in real Time Stability studies has been carried out for only one trail batch for Dexal capsule 30mg & 60mg.

Inspection Report M/s Dyson research laboratories 28 km, Ferozepur Road Lahore, applied for registration of Dexal Capsule 30mg& Dexal Capsule 30mg with following composition:

Dexal Capsule 30mg
Each capsule contains:
Dexlansoprazole…30mg, &

Dexal Capsule 60mg
Each capsule contains:
Dexlansoprazole…60mg,

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 along with the clarification of following point.
Why the dissolution test at 3rd month of Real Time stability studies has not been carried out for two stability batches for Dexal capsule 30mg (batch no. T02, T03) and Dexal capsule 30mg (batch no. T02, T03).

Composition of Panel:

1. Director, DTL, Lahore
2. Area FID, Lahore.
3. Mst. Haleema Sharif, Assistant Director, PEC, 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?	**Dexlansoperazole pellets 17% w/w:** Copy of commercial invoice stating following information is submitted by the firm. **ADC attestation date:**03-02-2017 **Exporter/manufacturer:** M/s Spansules Formulations, India. Batch No. DLT/SF/0010117 Quantity: 3.983 Kgs
2.	What was the rationale behind selecting the particular manufacturer of API?	Supplier was qualified based on pre-shipment samples, GMP certification, regulatory and documents compliant.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm imported Dexlansoerazole working standards from Everest Laboratories (Manufacturer of Dexlansoprazole API) through Indentor Neon Pharmaceuticals. The firm has submitted Invoices for purchase & Air way Bill for influx of Impurity Standards for both impurities: Sulphide, Sulphone. Invoice #: Exp/091/17-18 **Sulphide;** Batch # Sulphide/WS-01/17 Mfg: 10/17 Quantity: 100mg **Sulphone;** Batch # Sulphone/WS-01/17 Mfg: 10/17 Quantity: 100mg
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has submitted COAs of following APIs as obtained from source mentioned below: Dexlansoperazole pellets
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The applicant has submitted the following documents: **GMP Certificate:** **Issued to**: M/s Spansules Formulations, India. **Issued on**: 05-09-2018 **Issued by**: Drug Control Administration, Telangana, India. **Validity**: One year from the date of Issue.
6.	Do you use API manufacturer's method of testing for testing API?	The firm stated that they have used API testing method of source that is M/s Spansules Formulations, India.
7.	Do you have stability studies reports on API?	Yes
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes 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 calculating/quantify known impurities in API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of the API, reference standard and impurities standards (sulphone & shulphide Impurity standards).
11.	Have you used pharmaceutical grade excipients?	No excipients have been used in the manufacturing of applied formulation

<table>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>Firm has used ready to fill (semi-finished) dexlansoperazole pellets for fabrication of applied formulation; No excipients have been used in the manufacturing of applied formulation.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients used?</td><td>Firm has used ready to fill (semi-finished) dexlansoperazole pellets for fabrication of applied formulation; No excipients have been used in the manufacturing of applied formulation.</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development of Dexal 30mg & 60mg Capsule?</td><td>The firm has written and authorized protocols for the development of Dexal 30mg & 60mg Capsule.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-excipients compatibility studies?</td><td>N/A (Since firm is refilling pellets in capsules)</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has not performed comparative dissolution studies at three pH values that are 1.2, 4.5 and 6.8. Instead, they have performed comparative studies with the Innovator Product Dexilant capsule 30mg.
Batch #: 1503372
Mfg date: 12-2019
Exp date: 11-2019</td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>Yes, the firm has product development (R&D) section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Dexal 30mg & 60mg Capsule?</td><td>Yes, the firm has necessary equipment in R & D section though filling for the development of for Dexal 60 mg Capsule has been carried in General Production Capsule Section of the firm having commercial scale Capsule filling machine.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The equipment used in production and analysis of trial batches 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 Internal & External calibration program for the equipment used in production and QC.</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>Yes , the firm has qualified staff in product development section with proper knowledge and training in product development</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Dexal 30mg & 60mg Capsule as required?</td><td>The firm has manufactured following three stability batches for the stability studies of Dexal 30mg & 60mg Capsule
<table>
<tr><th>S. No.</th><th>Stability Batches</th><th>Batch Sizes</th></tr>
<tr><td>a.</td><td>T-01</td><td>2,200</td></tr>
<tr><td>b.</td><td>T-02</td><td>2,200</td></tr>
<tr><td>c.</td><td>T-03</td><td>2,200</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing batch size depend on the quantity required for 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.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>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.</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 adopted a Supplier method for testing of finished product which has been used in the stability</td></tr>
</table>

		studies. The firm has also submitted a report verifying the validation studies of the analytical method covering following parameters of validation: i. Specificity ii. Linearity iii. Precision iv. Ruggedness
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 equipment / 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.
30.	Do your HPLC software is 21CFR compliant?	Firm has 1 HPLC dedicated for R&D testing at the time of studies conducted and it is 21 CFR compliant. This HPLC system is used for stability studies of Dexal 30mg & 60mg Capsule. 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 Dexal 30mg & 60mg Capsule testing?	A complete trail of such testing was found available and verifiable from and software of HPLC.
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 stability batches kept on stability testing?	The firm has completed the accelerated stability testing on the three stability batches of Dexal 30mg & 60mg Capsule. Also the firm has stability batches kept on stability testing for the real time stability testing up to 12 months on all three batches of Dexal 30mg & 60mg Capsule.
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 Dexal 30mg & 60mg Capsule 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. Digital data loggers are available for continuous monitoring of temperature and humidity conditions of stability chamber.
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.
37.	"Dissolution test at 3rd month of Real Time stability studies has not been carried out for two stability batches for Dexal capsule 30mg (batch no. T02, T03) and Dexal capsule 30mg (batch no. T02, T03)."	1. Dissolution testing of batch No. T02 & T03 of both strengths 30 mg & 60 mg for real time study at 3rd month was missed unintentionally by confusion. 2. Testing of dissolution of batch No. T01 for both strengths 30 mg & 60 mg may be considered instead

		because the skipped batches have the same granules filled in capsules and maintained at real time study condition. 3. All other tests for T02 & T03 were performed on 3rd month, & were within limits. 4. We have submitted 9 months study of real time stability where T02 & T03 complied all the specifications, through 9 months period. 5. In the light of point 4, batch No T02 & T03 Complied dissolution specs at 6th & 9th months so though unintentional skipping of test at 3rd month was done but product is showing valid stability results. Company humbly request to consider all other testing at all time points a valid stability of products & grant please registration accordingly.

Conclusion & Recommendations

The firm was also advised to keep record of raw data of the stability testing.

On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Dexal Capsule 30mg & Dexal Capsule 60mg is verifiable to a satisfactory level. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suitable for the manufacturing of Dexal Capsule 30mg & Dexal Capsule 60mg, therefore, the panel recommends the registration of above stated product in the name of the manufacturerM/s Dyson research laboratories 28 km, Ferozepur Road Lahore.

Decision: Registration Board decided to approve registration of "Dexal Capsule 30mg & Dexal Capsule 60mg (Dexlansoprazole) by M/S. Dyson research laboratories, 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.

b. EXEMPTION FROM ONSITE VERIFICATION OF STABILITY DATA

943.	Name and address of manufacturer / Applicant	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Apiban 2.5mg tablet
	Composition	Each film coated tablet contains: Apixaban …… 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 97; 01-08-2016; Rs.20,000/- (01-08-2016)
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's,20's, 30's
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Not available
	GMP status	GMP certificate based upon evaluation conducted on 6-7-2017
	Remarks of the Evaluator	• Firm has submitted Form 5-D (dated 20-12-2017) alongwith differential fee of Rs. 30,000/- • Stability data as per directions of 251st meeting of Registration Board shall be submitted.
	Previous Decision	Registration Board in its 277th meeting deferred the case for submission of stability studies data as per directions of 251st meeting of Registration Board.
	Evaluation by PEC	Now the firm has submitted stability studies of the applied formulation.

STABILITY STUDY DATA

Drug	Apiban 2.5mg tablet
Name of Manufacturer	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.

API Lot No.	Lot No. 1704002291		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Accelerated: 06month Real Time: 06month		
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6 (Month)& ongoing		
Batch No.	RD-18101	RD-18102	RD-18103
Batch Size	7,600 Tabs	7,600 Tabs	7,600 Tabs
Manufacturing Date	02-05-2018	02-05-2018	02-05-2018
Date of Initiation	06-2018	06-2018	06-2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted Photocopy of COA of Apixaban having following information on it. **For API Apixaban:** **Batch No**: 1704002291 **Manufacturer:**M/s Alembic Pharmaceuticals Limited, India.
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.	Firm has submitted following: **Copy of GMP certificate for Apixaban Manufacturer:** Issued To: M/s. Alembic Pharmaceuticals, India. Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India. Issued On: 02 August, 2016 Valid up till: 01-08-2018.
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.	Applicant has submitted ADC attested invoice stating following information on it: **For Apixaban:** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
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
Apixaban 2.5mg Tablets

Administrative Portion

01	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has quoted the onsite panel inspection for Nebvax (Nebivolo + Valsartan) 5/80mg Tablet, Daplozmet 5/850mg Tablet & Daplozmet 5/1000mg Tablet conducted on 1st January, 2019 & presented in 288th RB meeting as a reference inspection for instant dosage form. 1. 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. 2. Is proper and continuous monitoring and control available for stability chamber? — Yes, monitoring and control was available for the stability chambers provided. Firm was advised to install alarm system in stability chamber and perform challenge test.
02	Documents for the procurement of API with approval from DRAP (in case of import).	Applicant has submitted ADC attested invoice stating following information on it: **For Apixaban:** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
03	Documents for the procurement of reference standard and impurity standards.	.
04	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted following: **Copy of GMP certificate for Apixaban Manufacturer:** Issued To: M/s. Alembic Pharmaceuticals, India. Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India. Issued On: 02 August, 2016 Valid up till: 01-08-2018.
05	Mechanism for Vendor pre-qualification.	Firm has submitted Vendor Qualification Flow Chart.
06	Certificate of analysis of the API, reference standards and impurity standards.	**For API Apixaban:** Photocopy of COA of Batch No. 1704002291 issued by M/s Alembic Pharmaceuticals Limited, India is submitted. **Working standards:** The firm has submitted the copy of COA of working Standards (Apixaban) Batch No. WS/APN/001, Quantity 0.2gm, provided by the API Manufacturer - M/s Alembic Pharmaceuticals Limited, India is submitted.
07	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients used in product development.

<table>
<tr><td>08</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted list of 06 qualified person working in R&D section.</td></tr>
<tr><td colspan="3">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 copy of generalized SOP with the title ‘Product Design & Development’, Effective Date: 10th April,2017, & Analytical method for testing of API & FPP.</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided batch manufacturing record of all the three batches
<table>
<tr><th colspan="4">Apixaban 2.5mg Tablets</th></tr>
<tr><th>BATCH NO.</th><th>BACH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr>
<tr><td>RD-18101</td><td>7,600 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
<tr><td>RD-18102</td><td>7,600 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
<tr><td>RD-18103</td><td>7,600 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
</table></td></tr>
<tr><td>11</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Apixaban 2.5mg Tablets; Stability Pack Size : 2 x 14’s)
• RD-18101: Batch Size : 7,600 Tablets
Number of tablets blistered: 400
12 Packs placed on stability (Accelerated: 03 Packs, Real Time : 09 Packs), out of which 01 pack are remaining Accelerated and 06 Packs remaining Real Time.
• RD-18102: Batch Size : 7,600 Tablets
Number of tablets blistered: 400
12 Packs placed on stability (Accelerated: 03 Packs, Real Time : 09 Packs), out of which 01 pack are remaining Accelerated and 06 Packs remaining Real Time.
• RD-18103: Batch Size : 7,600 Tablets
Number of tablets blistered: 400
12 Packs placed on stability (Accelerated: 03 Packs, Real Time : 09 Packs), out of which 01 pack are remaining Accelerated and 06 Packs remaining Real Time.</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis.</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.</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) stability study reports of 03 batches of Apixaban from M/s Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Village Karakhadi, Taluk-Padra, District-Panchmahal Vadodara-391450, Gujarat, India.</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 Drug-excipients compatibility studies</td></tr>
<tr><td>18</td><td>Record of comparative dissolution</td><td>Firm has submitted comparative dissolution profile with the</td></tr>
</table>

<table>
<tr><td></td><td>data.</td><td>reference product Eliquis 2.5mg Tablet, Bristol-Myers Squibb, USA.
<table>
<tr><th>FEATURE</th><th>REFERENCE PRODUCT</th><th>PRODUCT OF HIGHNOON</th></tr>
<tr><td>BRAND NAME</td><td>Eliquis 2.5mg Tabs.</td><td>Apixaban 2.5mg Tabs.</td></tr>
<tr><td>BATCH #</td><td>AAM5629</td><td>RD-18102</td></tr>
<tr><td>MFG/EXPIRY</td><td>Mfg. Date: 08-2016
Exp. Date: 07-2019</td><td>Mfg. Date: 05-2018
Exp. Date: 05-2020</td></tr>
</table></td></tr>
<tr><td>19</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.</td></tr>
</table>

Evaluation by PEC:

Sr. No.	Deficiencies	Justification
1.	Documents for the procurement of reference standard and impurity standards are not submitted, clarify/Justify	The related substances in API % FPP are evaluated by the validated method the related substance is calculated by relative retention time which does not require impurity standard. For identification of the known impurities (Impurity A, Impurity B, Impurity C, Impurity D) the relative retention time (i.e. with reference to Apixaban: Impurity A= about 2.19; Impurity B= about 0.45; Impurity C= about 1.26; Impurity D= about 2.82; Apixaban= about 1.00) is used. The API Manufacturer testing procedure and highnoon method of testing for finished product are attached for reference A-1.
2.	Batch size for each of three trials is 3800 tablets as per you reconciliation sheet; out of which 400 tablets are blistered, 350 tablets were kept on stability. Justify/clarify that 350 tablets are sufficient for test/ analysis of each of the trials at all time points up till proposed shelf life. Moreover, where the remaining tablets which were not blistered were kept?	Total Tablets required for Dissolution=6 Disintegration=6 Assay/Purity=30 Total Tablets=42 Total Intervals (Real Time Stability)=6 Total Intervals (Accelerated Stability)=2 Total Intervals=8 Total Tablets Required=8*42=336 So total 350 tablets are placed in stability and the no of required tablets for testing are 336 and remaining quantities of the tablets are with the product Development Department.
3.	Analytical method used for test/analysis of applied drug product is in house or supplier, Clarify.	The method is in-house and is validated. The analytical method validation report was submitted in file no.1, Annex 13. However a copy of report is enclosed.
4.	Submit stability data of API by its manufacturer, as it is not submitted.	The stability data is enclosed.
5.	Time intervals for sampling in CDP are 10, 20, 30, & 45 minutes, which are different from that recommended by guidelines, clarify/justify.	As per item 10.3.3 of WHO Technical Report series No.992, 2015, Annes & Multisource (generic) pharmaceutical products; guidelines on registration requiremets to establish interchangeability. "10.3.3 Disssolution profile comparison for biowavers based on dose-proportionality of formulation As for biowaivers based on BCS, a model independent mathematical approach (e.g. F2 test) can used for comparing the dissolution profiles fo two products. The dissolution of the two products

		(reference strength and additional strength) should be measured under the same test condition. The dissolution sampling times for both reference strength and additional strength profiles should be the same for example. • Fro immediate release products 5,10,15,20,30,45 and 60 minutes. • For 12 hour extended release products 1,2,4,6,8 and 12 hours • For 24 hour extended release products 1,2,4,6,8,16 and 24 hours.
6.	Evidence of purchase of reference product eliquis for CDP.	Receipt for Eliquis purchase (enclosed)
7.	Submit chromatograms for 3rd month accelerated stability studies for all three trial batches.	The chromatograms are attached in Annexure 16 of already submitted file NO.2. However copies of chromatogram for 3rd month accelerated stability studies for all three trial batches are attached for your reference.
8.	According to information on chromatograms: In initial studies of batch 18101, Assay is performed on 29th May, 2018 & dissolution on 2nd June 2018, clarify/justify before further processing of the case.	Due to overload of work the testing of batch was planned in parts according to the availability of the equipment. Therefore after performing assay testing on 29th of May, 2018 dissolution testing was planned on 2nd June 2018.

Decision: Registration Board decided to defer the case for confirmation of audit trail of HPLC analysis For stability studies of all three trial batches of applied product & clarification as all three trials of both stregths of Apiban tablet 2.5mg & 5mg have same audit trial in terms of date & time at all time intervals for all injections of sample & standard, by Area FID and respective evaluator, PEC.

944.	Name and address of manufacturer / Applicant	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Apiban 5mg tablet
	Composition	Each film coated tablet contains: Apixaban …… 5mg
	Diary No. Date of R& I & fee	Dy. No. 96; 01-08-2016; Rs.20,000/- (01-08-2016)
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's,20's, 30's
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Not available
	GMP status	GMP certificate based upon evaluation conducted on 06-07-2017.
	Remarks of the Evaluator	• Firm has submitted Form 5-D (dated 20-12-2017) alongwith differential fee of Rs. 30,000/- • Stability data as per directions of 251st meeting of Registration Board shall be submitted.
	Previous Decision	Registration Board in its 277th meeting deferred the case for submission of stability studies data as per directions of 251st meeting of Registration Board.
	Evaluation by PEC	Now the firm has submitted stability studies of the applied formulation.

STABILITY STUDY DATA

Drug	Apiban 5mg tablet
Name of Manufacturer	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.
API Lot No.	**Lot No.** 1704002291

Description of Pack (Container closure system)	2×14's: Alu-alu blister		
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH		
Time Period	Accelerated: 6 Month Real Time: 6 Month		
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	RD-18092	RD-18093	RD-18094
Batch Size	3800 Tablets	3800 Tablets	3800 Tablets
Manufacturing Date	05, 2018	05, 2018	05, 2018
Date of Initiation	06, 2018	06, 2018	06, 2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted Photocopy of COA of Apixaban having following information on it. **For API Apixaban:** **Batch No**: 1704002291 **Manufacturer:**M/s Alembic Pharmaceuticals Limited, India.
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.	Firm has submitted following: **Copy of GMP certificate for Apixaban Manufacturer:** Issued To: M/s. Alembic Pharmaceuticals, India. Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India. Issued On: 02 August, 2016 Valid up till: 01-08-2018.
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.	Applicant has submitted ADC attested invoice stating following information on it: **For Apixaban:** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
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	Yes

	assigned shelf life of the product.	
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Data for exemption from On-site investigation of submitted stability data
Apixaban 5mg Tablets

Administrative Portion

01	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has quoted the onsite panel inspection for Nebvax (Nebivolo + Valsartan) 5/80mg Tablet, Daplozmet 5/850mg Tablet & Daplozmet 5/1000mg Tablet conducted on 1st January, 2019 & presented in 288th RB meeting as a reference inspection for instant dosage form. 1. 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. 2. Is proper and continuous monitoring and control available for stability chamber? — Yes, monitoring and control was available for the stability chambers provided. Firm was advised to install alarm system in stability chamber and perform challenge test.
02	Documents for the procurement of API with approval from DRAP (in case of import).	Applicant has submitted ADC attested invoice stating following information on it: **For Apixaban:** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
03	Documents for the procurement of reference standard and impurity standards.	
04	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted following: **Copy of GMP certificate for Apixaban Manufacturer:** Issued To: M/s. Alembic Pharmaceuticals, India. Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India. Issued On: 02 August, 2016 Valid up till: 01-08-2018.
05	Mechanism for Vendor pre-qualification.	Firm has submitted Vendor Qualification Flow Chart.
06	Certificate of analysis of the API, reference standards and impurity standards.	**For API Apixaban:** Photocopy of COA of Batch No. 1704002291 issued by M/s Alembic Pharmaceuticals Limited, India is submitted. **Working standards:** The firm has submitted the copy of COA of working Standards (Apixaban) Batch No. WS/APN/001, Quantity 0.2gm, provided by the API Manufacturer – M/s Alembic Pharmaceuticals Limited, India is submitted.
07	Documents for the procurement of excipients used in product	Firm has submitted documents for procurement of excipients used in product development.

<table>
<tr><td></td><td>development?</td><td></td></tr>
<tr><td>08</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted list of 06 qualified person working in R&D section.</td></tr>
<tr><td colspan="3">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 copy of generalized SOP with the title ‘Product Design & Development’, Effective Date: 10th April, 2017, & Analytical method for testing of API & FPP.</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
<table>
<tr><th colspan="4">Apixaban 2.5mg Tablets</th></tr>
<tr><th>BATCH NO.</th><th>BACH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr>
<tr><td>RD-18092</td><td>3,800 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
<tr><td>RD-18093</td><td>3,800 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
<tr><td>RD-18094</td><td>3,800 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
</table></td></tr>
<tr><td>11</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Apixaban 5mg Tablets; Stability Pack Size : 2 x 7’s)
• RD-18092: Batch Size : 3,800 Tablets
Number of tablets blistered: 400
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 01 pack are remaining Accelerated and 12 Packs remaining Real Time.
• RD-18093: Batch Size : 3,800 Tablets
Number of tablets blistered: 400
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 01 pack are remaining Accelerated and 12 Packs remaining Real Time.
• RD-18094: Batch Size : 3,800 Tablets
Number of tablets blistered: 400
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 01 pack are remaining Accelerated and 12 Packs remaining Real Time.</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.</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) stability study reports of 03 batches of Apixaban from M/s Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Village Karakhadi, Taluk-Padra, District-Panchmahal Vadodara-391450, Gujarat, India.</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 Drug-excipients compatibility studies</td></tr>
<tr><td>18</td><td>Record of comparative dissolution</td><td>Firm has submitted comparative dissolution profile with the</td></tr>
</table>

<table>
<tr><td></td><td>data.</td><td>reference product Eliquis 5mg Tablet, Bristol-Myers Squibb, USA.
<table>
<tr><th>FEATURE</th><th>REFERENCE PRODUCT</th><th>PRODUCT OF HIGHNOON</th></tr>
<tr><td>BRAND NAME</td><td>Eliquis 5mg Tabs.</td><td>Apixaban 5mg Tabs.</td></tr>
<tr><td>BATCH NO.</td><td>AAX1407</td><td>RD-18093</td></tr>
<tr><td>MFG./ EXPIRY DATE</td><td>Mfg. Date: 01-2018
Exp. Date: 12-2020</td><td>Mfg. Date: 05-2018
Exp. Date: 05-2020</td></tr>
</table></td></tr>
<tr><td>19</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.</td></tr>
</table>

Evaluation by PEC:

Sr. No.	Deficiencies	Justification
1.	Submit Valid copy of GMP certificate of API Manufacturer issued by concerned regulatory authority of country of origin, as it is not valid now.	The GMP certificate for Apixaban (1809992) issued to alembic pharmaceutical Ltd, Valid up to 05-9-2021 is attached.
2.	Batch size for each of three trials is 7600 tablets as per your reconciliation sheet; out of which 400 tablets are blistered, 364 tablets were kept on stability. Justify/clarify that 364 tablets are sufficient for test/ analysis of each of the trials at all time points up till proposed shelf life. Moreover, where the remaining tablets which were not blistered were kept?	Total Tablets required for Dissolution=6 Disintegration=6 Assay/Purity=30 Total Tablets=42 Total Intervals (Real Time Stability)=6 Total Intervals (Accelerated Stability)=2 Total Intervals=8 Total Tablets Required=8*42=336 So total 364 tablets are placed in stability and the no of required tablets for testing are 336 and remaining quantities of the tablets are with the Product Development Department.
3.	Documents for the procurement of following excipients; macrogol 600, lactose anhydrous, polysorbate 80, titanium dioxide, iron oxide yellow, colloidal silicon dioxide are not submitted.	All the above excipients are procured from local vendors and their COAs are submitted in Annex 12 of already submitted file 1. The copies of COAs for your reference are enclosed.
4.	Submitted stability data of API by its Manufacturer, as it is not submitted.	The stability data is enclosed.
5.	Trial RD-18092 , RD-18093 & RD-18094 is prepared on 2nd May 2018 & assay testing is carried out on 29th May 2018 & dissolution on 2nd June 2018 as per information on chromatograms, Clarify/Justify,	Due to overload of work the testing of batch was planned in parts according to the availability of the equipment. Therefore after performing assay testing on 29th of May, 2018 dissolution testing was planned on 2nd June 2018.
6.	Chromatograms for Trial RD-18092 & RD-18093 at initial studies are not of applied drug product instead they are of some other formulation & contain a different batch number, Clarify/Justify before further processing of case.	The batch numbers mentioned on sample chromatograms are as per batch numbers were mentioned collectiverly because same standard is used against multiple samples analysed on same day. As products development has developed different formulations other thatn those formulation submitted, so batch numbers of those trials (formulation) were also mentioned on standards.
7.	Chromatogram for blank solution for trial 18093 at 6th month Accelerated Stability Studies shows some upward & downward peaks. Clarify/Justify	Based on your query we reviewed chromatogram of blank. As the diluents may have very minor residues therefore for the ease of review its scale is normalized at 1 mAU along Y axis whereas in sample chromatogram due the very high concentration of solute its scale is normalized at 80

		mAU along y-axis. So the baseline looks like that due to low scale)1/80th of the scale used for sample.) For understanding thechromatogram of blank solution normalized at 80 mAU is attached check A-4.
8.	Baseline for reference standards is not stable. Clarify/Justify.	Based on your we reviewed all datat and we found that in the chromatogram of reference solution of related substances, there is low concentration , its scale is normalized at 10mAU along Y axis whereas in sample chromatogram due to very high concentration its scale is noramlized at 1700mAU along y-axis. So the baseline looks like that at low scale. For understanding the chromatogram of reference solution narmalized at 1700mau is attached.
9.	Date & time for both strengths of Apixaban 2.5mg & 5mg tablet are same as per chromatograms & Audit trail. Justify/Clarify.	As the manufacturing of both strengths of Apixaban2.Smg &5mg are same as well as testing procedure is also same so we planned their analysis at same date and time

Decision: Registration Board decided to defer the case for confirmation of audit trail of HPLC analysis. For stability studies of all three trial batches of applied product & clarification about how it is possible for all three trials of both stregths of Apiban tablet 2.5mg & 5mg to have same audit trial in terms of date & time at all time intervals for all injections of sample & standard, by Area FID and respective evaluator, PEC.

945.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt.) Ltd, Karachi
	Brand Name +Dosage Form + Strength	Empag M 12.5mg + 1000mg Tablets
	Composition	Each Extended Release Film Coated Tablet Contains: - Empagliflozin ……12.5mg Metformin hydrochloride…1000mg
	Diary No. Date of R& I & fee	Dy No.34140; 15-10-2018: 50,000/- ; 09-10-18
	Pharmacological Group	Anyti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (Synjardy XR Tablet)
	Me-too status	N/A
	GMP status	In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other CGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an satisfactory level of compliance with CGMP GUIDLINES as of today. The management was also suggested to further strengthen stability and analytical sections

STABILITY STUDY DATA

Drug	Empag M 12.5mg /1000mg Tablets
Name of Manufacturer	Genix Pharma (Pvt.) Ltd, Karachi
Manufacturer of API	**For Empagliflozin:** M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China has been submitted. **For Metformin HCl:** M/s Wanbury Limited, India
API Lot No.	Empagliflozin: Lot #: EGLZ-RD20171101A Metformin Hydrochloride Lot #: MT00600118

Description of Pack (Container closure system)	Alu /alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	18SB-103-01	18SB-104-02	18SB-105-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	26-06-2018		
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Photocopy of COAs of Empagliflozin &Metformin hydrochloride for following batches have been submitted. **Particulars Batch No.** Empagliflozin EGLZ-RD20171101A Metformin Hydrochloride MT00600118
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.	Applicant has submitted the following: **For Empagliflozin:** GMP Certificate No: 2018024 Issued to: Ruyuan HEC Pharm Co., LTD Issued by: Shaoguan Food & Drug Administration Validity: Until 18-12-2019 **For Metformin HCl:**
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.	Applicant has submitted the following: **For Empagliflozin:** Copy of commercial Invoice declaring following information on it: Invoice No: WIS170152 Attested by: ADC Karachi Attested on: 07-12-2017 Quantity: 0.75 Kg From: M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China. **For Metformin HCl:** Copy of commercial Invoice declaring following

		information on it: Invoice No: EXP/92001577/ 17-18 Attested by: ADC Karachi Attested on: 30-1-2018 Quantity: 5000 Kg From: M/s Wanbury Limited, India.
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 onsite 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 "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 06-02-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide), of M/s. Genix Pharma (Pvt.) Ltd., Karachi. Following two points are reported inside the above stated inspection report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. (Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well).
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Applicant has submitted the following: **For Empagliflozin:** Copy of commercial Invoice declaring following information on it: Invoice No: WIS170152 Attested by: ADC Karachi Attested on: 07-12-2017 Quantity: 0.75 Kg From: M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China has been submitted. **For Metformin HCl:** Copy of commercial Invoice declaring following information on it: Invoice No: EXP/92001577/ 17-18 Attested by: ADC Karachi Attested on: 30-1-2018 Quantity: 5000 Kg From: M/s Wanbury Limited, India

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><u>For Empagliflozin:</u>
The firm has submitted copy of letters from M/s Ruyuan HEC Pharm Co., Ltd. China in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th></tr><tr><td>Working standard</td><td>EGLZ-WS201612101</td><td>2gm</td></tr></table><u>For Metformin HCl:</u>
M/s USP 7135 English Muffin Way Frederick, MD 21704, USA in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th></tr><tr><td>Working standard</td><td>--------</td><td>200mg</td></tr></table></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>Applicant has submitted the following:
<u>For Empagliflozin:</u>
GMP Certificate No: 2018024
Issued to: Ruyuan HEC Pharm Co., LTD
Issued by: Shaoguan Food & Drug Administration
Validity: Until 18-12-2019
<u>For Metformin HCl:</u></td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for Selection of manufacturer for Vendor Certification.
SOP No: QA/SOP/SY/037 with effective date 07-10-2016.
Version no: 01
Copy of “Vendor’s Audit form” filled for M/s Ruyuan HEC Pharm Co., Ltd. China.
Copy of “Vendor’s Audit form” filled for M/s Wanbury Limited. India.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Empagliflozin, working standards and impurity standards issued by M/s Ruyuan HEC Pharm Co., Ltd. China. & M/s USP 7135 English Muffin Way Frederick, MD 21704 is submitted. Detail is as under :<table><tr><th>Particulars</th><th>Batch No</th></tr><tr><td>Empagliflozin</td><td>EGLZ-RD20171101A</td></tr><tr><td>Metformin Hydrochloride</td><td>MT00600118</td></tr><tr><td colspan="2">Working Standards</td></tr><tr><td>Empagliflozin</td><td>EGLZ-WS201612101</td></tr><tr><td>Metformin HCl</td><td>R069H0</td></tr><tr><td colspan="2">Impurity Standards</td></tr><tr><td>Melamine</td><td>GIM492</td></tr><tr><td>Metformin Related Compound A</td><td>R072Y0</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 photocopy of Purchase Order/Invoices for the 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>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 04 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 Development Protocol for Lab scale batch manufacturing of Empag-M Tablets (12.5mg + 1000mg).</td></tr>
</table>

<table>
<tr><td></td><td></td><td>The master formulation and manufacturing method mentioned in development protocol is same as that of reference product.</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 the following 03 Batches:
<table>
<tr><th>BATCH NO</th><th>BATCH SIZE</th><th>MFG DATE</th></tr>
<tr><td>18SB-103-01</td><td>1500 Tablets</td><td>04-2018</td></tr>
<tr><td>18SB-104-02</td><td>1500 Tablets</td><td>04-2018</td></tr>
<tr><td>18SB-105-03</td><td>1500 Tablets</td><td>04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has attached Record of remaining quantities of 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>The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 01-03-2018 to 31-10-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td><u>For Empagliflozin:</u>
The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Empagliflozin.
<u>For Metformin HCl:</u>
The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Metformin HCl.</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 (QC-FPNS-135 issued on 10-04-2018) for Empag M Tablets (12.5mg + 1000mg) along with Stability Study Report of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td><u>For Empagliflozin:</u>
The firm has submitted photocopy of Empagliflozin 06 Months Accelerated (40oC+2 oC, RH 75+5%) Data of 03 Batches of from M/s Ruyuan HEC Pharm Co., Ltd. China.
<u>For Metformin HCl:</u>
Metformin HCl 06 Months Accelerated (40oC+2 oC, RH 75+5%) and 72Months Real Time Stability Study (30oC+2 oC, RH 65+5%) of Metformin HCl from M/s Wanbury Limited. India.</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 Empag-M Tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has stated that the composition of developed product is similar to the innovator’s product formulation, no ingredient which could have adverse effects over product’s in-vivo performance is used during product development therefor, it is presumed that used inactive ingredients are compatible with the active (Empagliflozin+ Metformin HCl) & also with each other and this is ensured by satisfactory results from formal stability studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted F2 factor protocol (QC/PRO/CD/21) & reports dated 03-12-2018. The details of reference product & Sample product are as follows:
<table>
<tr><th>feature</th><th>Reference product</th><th>Product of M/S Genix Pharma</th></tr>
<tr><td>Brand name</td><td>Synjardy Tablet</td><td>Empag-M Tablets</td></tr>
</table></td></tr>
</table>

		5mg/1000mg | 5mg +1000mg Batch No | 605012 | 18SB-097-01 Expiry Date | 12-2020 | 04-2020 Comparative dissolution studies have been performed in following mediums: i. pH 0.1N HCl buffer ii. pH 4.5 Acetate buffer iii. pH 6.8 Phosphate buffer In pH 0.1 N HCl buffer similarity factory is 87.083 In pH 4.5 Acetate buffer similarity factory is 84.201 In pH 6.8 Phosphate buffer similarity factory is 83.539
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

Remarks of Evaluator :

Sr.#	Deficiencies	Justification
1.	You are acquiring Metformin Hcl from M/s Wanbury, a pharmaceutical unit located in Maharashtra state of India as per commercial invoice, but submitted GMP certificate is of another site of same manufacturer located in Andhra-Pardesh. Submit GMP certificate of desired site.	M/s Wanbury, Head office located in Maharashtra state while manufacturing unit located in Andhra-Pardesh. This address is also mentioned on commercial invoice, COA and GMP. Reference attached (Annexure point no. 1)
2.	You have procured four lots of Metformin Hcl as per invoice; also submit the record about which lot is used in the manufacturing of trial batches.	The batch number MT00600118 is used. COAs and BMRs are attached for reference. Annexure point No.2
3.	COA for one lot of Metformin Hcl is submitted, but you have procured four lots, as per submitted commercial invoice, clarify/justify	Genix Pharma is also manufacturing other combination products like Metformin Hcl and Sitagliptin Phosphate Tablets Range. That's why Metformin Hcl is used from commercial material.
4.	How would you have come to know about batch number of Empagliflozin, one of the APIs of applied drug product, as it is not mentioned on commercial invoice. Clarify/Justify.	The clarification letter from supplier with purchase invoice is attached as reference (Annexure Point no 4)
5.	What analytical method you are using for test/ Analysis of applied drug product either in-house or supplier.	The in-house validated method is used for analysis of finished product (Annexure Point no 5)
6.	Evidence of procurement of reference product Synjardy XR?	Purchase invoice attached (Annexure Point no 6)
7.	Submit Raw data sheets for dissolution and assay testing along with chromatograms at every time points because raw data sheet submit separately which are difficult to understand.	Complete dissolution and assay testing along with chromatograms are attached in file (Annexure Point no 7)
8.	In dissolution testing, Empagliflozin is quantified by HPLC & Metformin Hcl is quantified by UV method as per your FPP Specification. Justify.	Empagliflozin cannot be detectable due to its lowest concentration with respect to metformin Hcl. That's why dissolution is conducted on HPLC while Metformin Hcl can be detected without any interference. Dissolution of Metformin Hcl extended release tablets are also given in USP by Spectroscopy method.
9.	Submit spectrums for dissolution testing of metformin Hcl, if you have quantified it on UV.	UV data of Metformin Hcl is attached in separate file (Annexure Point no 7)
10.	In dissolution testing, Empagliflozin is quantified by	The dissolution of Empagliflozin was conducted

	HPLC & Metformin Hcl is quantified by UV Spectrophotometric Method as per your FPP Specification, but all chromatog-Uiorams for dissolution testing shows peaks for both APIs. Clarify/Justify.	as per assay method that's why tablets contained to APIs showing its absorbance Metformin Hcl and Empagliflozin.
11.	Date acquired 29th of June 2018 on chromatograms for run of sample of content uniformity test at initial studies of trial no 18SB-112-01CU03 of applied drug product is not verifiable from the submitted audit trial reports some others chromatograms are not verifiable form submitted audit trial reports. Clarify/Justify	Audit Trial reports of content uniformity are attached (Annexure Point no 11)
12.	Details of equipment used for applying layer of Empagliflozin over Metformin Hcl Extended release core, is required to be submitted	(Attached in Annexure Point no 12)

Decision: Deferred for clarification regarding compensation of manufacturing loss during coating of API(Empagliflozin) over extended release core(Metformin hydrochloride) as there is no any overage mentioned in master formulation to compensate for manufacturing/process loss of API during coating.

946.	Name and address of manufacturer / Applicant	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Betanorm Plus Tablets 5/80mg
	Composition	Each film coated tablet contains: Nebivolol as hydrochloride…5mg Valsratan…….80 mg
	Diary No. Date of R& I & fee	Dy.No. dated 09-03-2017 Rs.20, 000/- for Form 5 Dated 09-03- 2017 Dy. No_____ dated 03-04-2017 differential fee of Rs.30,000/- for Form 5D Dated 03-04- 2017
	Pharmacological Group	B-adrenergic Receptor blocking Agent, Angiotensin II Receptor Blocker
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	GMP status	GMP Inspection conducted on 02-02-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

	STABILITY STUDY DATA SUBMITTED INITIALLY	
	Drug	Betanorm Plus Tablets 5/80mg
	Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Manufacturer of API	**Nebivolol as hydrochloride:** M/s Cadila pharmaceuticals Limited. **Valsartan:** M/s Zhejiang Tianyu Pharmaceutical Co., China.
	API Lot No.	**Nebivolol as hydrochloride:** **Lot #:** 17NV016 **Valsartan:** **Lot #:** 10240-170702
	Description of Pack (Container closure system)	Alu /PVC Blister Pack in Unit carton

	Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH			
	Time Period	Accelerated: 6 Months Real Time: 9 Months			
	Frequency	Real Time: 0,3, 6,9,12,18 & 24 (months) Accelerated: 0,3 & 6 (months)			
	Batch No.	Trial# 01	Trial# 02	Trial# 03	
	Batch Size	1500 Tablets	1500 Tablets	1500 Tablets	
	Manufacturing Date	11/2017	11/2017	12/2017	
	Date of Initiation	02/12/2017	07/12/2017	13/12/2017	
	No. of Batches	03			
Date of Submission		Dy No. 39212: 28/11/2018			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr. No.	Documents To Be Provided	Status
1	COA of API.	Firm has submitted the following: **Nebivolol as hydrochloride:** Copy of COA: Batch #: 17NV016 Manufacturer: M/s Cadila Pharmaceuticals Ltd, India. **Valsartan:** Copy of COA: Batch #:10240-170702) Manufacturer: M/s Zhejiang Tianyu Pharmaceuticals Co, Ltd, China.
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.	Firm has submitted the following: **Nebivolol as hydrochloride:** Copy of GMP certificate: Certificate No.180686 Issued by: India Food & Drugs Control Administration, India. Validity: until 20/12/2018 **Valsartan:**Copy of GMP certificate: Certificate No. Zj20130111 Issued by: China Food & Drugs Administration, china. Validity: until 09/12/2018
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 the following: **Nebivolol as hydrochloride:** Copy of commercial invoice: Dated: 31-07-2017 **Valsartan:** Copy of commercial invoice: Dated: 17-08-2017 attested by ADC, 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
	Data for 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: 28-11-2018 vide diary No. 28-11-18.	
	Administrative Portion	
1	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th &finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed. ● The firm has 21CFR compliant HPLC software. ● The firm has audit trail reports available.
2	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted the following: **For Nebivolol hydrochloride:** Copy of commercial invoice: Dated: 31st of July, 2017. Attested on: 31st of August, 2017. Attested By: ADC, DRAP Islamabad. Quantity of API: 5kgs Nebivolol hydrochloride. Batch #: 17NV016 **For Valsartan:** Copy of commercial invoice: Dated: 11th of August 2017. Attested on: 06th of August, 2017. Attested By: ADC, DRAP Islamabad. Quantity of API: 500kgs. Batch #: 10240-170701/10240-170702.
3	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard & impurity Standards: **For working standard:** Nebivolol hydrochloride : 100.5 % Valsartan: 99.7% **For Impurity standard:** Valsartan Related compound A: 99.9% Valsartan Related compound B: 98.3 % Valsartan Related compound C: 99 %
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 certificates declaring following information: **For Nebivolol as hydrochloride:** Certificate No.180686 Issued to: M/s Cadila Pharmaceutical Ltd, 294, G.I.D.C Estate, Ankleshwar-393 002, District- Bharuch. India. Issued by: Food & Drug Control Administration, Gujarat State, India. Validity: Valid Till 20-12-2018. **For Valsartan:** Certificate No. ZJ 20130111 Issued to: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd, China.

<table>
<tr><td></td><td></td><td>Issued by: State Food & Drug Administration, China.
Validity: Valid Till 09-12-2018.</td></tr>
<tr><td>5</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted copy of SOP for Evaluation of Vendors.</td></tr>
<tr><td>6</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Applicant has submitted following COAs:
<u>APIs:</u>
<u>For Nebivolol hydrochloride:</u>
Copy of COA of API
Batch # 17NV016
From: M/s Cadila Pharmaceutical Ltd, India.
<u>For Valsartan:</u>
Copy of COA of API
Batch # 10240-170702
From: M/s Zhejiang Tianyu Pharmaceutical Co., Ltd, China.
<u>For Reference Standards:</u>
Copy of COA of Nebivolol hydrochloride
Copy of COA of Valsartan
<u>For Working Standards:</u>
Copy of COA for Valsartan impurity Standards A, B & 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 all the excipients used in the formulation of applied product.
Commercial invoice dated 01-11-17 for Microcrystalline cellulose. 200.
Commercial invoice dated 17-11-16 for HPMC.
Commercial invoice dated 14-01-17 for Talcum.
Commercial invoice dated 19-04-17 for Sodium Starch Glycolate.
Commercial invoice dated 03-11-16 for Magnesium Stearate.
Commercial invoice dated 25-09-17 for Titanium Dioxide.
Commercial invoice dated 25-09-17 for Polysorbate tween.
Commercial invoice dated 24-07-17 for Color Red # 40.</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.</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 “Work Instructions” for the Development of Betanorm Plus Tablets 5/80mg”.</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><th></th></tr>
<tr><td>Trial # 01</td><td>1500 tablets</td><td>Nov-17</td><td></td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>Nov-17</td><td></td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>Dec-17</td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td rowspan="4">11</td><td rowspan="4">Record of remaining quantities of stability batches.</td><td>Trial No</td><td>Total no. of Tablets For stability testing</td><td>Tablets used for testing</td><td>Remaining Quantities of tablets</td></tr>
<tr><td>Trial # 01</td><td>1246 Tab (41 packs * 30’s)</td><td>210 (7packs * 30’s)</td><td>1036 (34 packs * 30’s)</td></tr>
<tr><td>Trial # 02</td><td>1226 Tab (40 packs * 30’s)</td><td>210 (7packs * 30’s)</td><td>1016 (33 packs * 30’s)</td></tr>
<tr><td>Trial # 03</td><td>1232 Tab (41 packs * 30’s)</td><td>210 (7packs * 30’s)</td><td>1022 (34 packs * 30’s)</td></tr>
<tr><td colspan="6">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 colspan="4">Firm has submitted photocopies of data logger record temperature & humidity for chambers used in Real Time & Accelerated stability studies of applied product from 01-12-2017 to 31-08- 2018.</td></tr>
<tr><td>13</td><td>Method used for analysis of API along with COA.</td><td colspan="4">The firm has submitted photocopies of following: Raw Material Test/Analysis Procedures & Raw Material Specifications Of Nebivolol hydrochloride (In-house) and Valsartan (USP).
COAs for Nebivolol hydrochloride & Valsartan (Supplier/Manufacturer).</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 colspan="4">The firm has submitted photocopies of following:
FPP Test/Analysis Method & FPP Specifications (In-house) for Betanorm Plus 5/80mg tablet.
Firm has submitted method validation studies on following parameters:
Specificity
Linearity
Accuracy
Robustness
Precision</td></tr>
<tr><td>15</td><td>Reports of stability studies of API from manufacturer.</td><td colspan="4">The firm has submitted photocopy of 06 Months Accelerated and 18 Months Real Time Stability Study Data of 03 Batches of Nebivolol HCl from M/s Cadila Pharmaceutical Ltd, India according to zone IVA conditions.
The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Valsartan from M/s zhejiang Tianyu Pharmaceutical Co., Ltd, China according to zone IVA conditions.</td></tr>
<tr><td>16</td><td>Analysis reports for excipients used.</td><td colspan="4">The firm has submitted copy of Analytical reports of excipients used.</td></tr>
<tr><td>17</td><td>Drug-excipients compatibility studies.</td><td colspan="4">Applicant is referring to handbook of Pharmaceutical excipients & innovator Product (Byvalsont tablet) & stability studies as an evidence of Drug-excipients compatibility.</td></tr>
<tr><td>18</td><td>Record of comparative dissolution data.</td><td colspan="4">The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Byvalson Tablets 5/80mg distributed by M/S. Allergan USA with Lot No.W00551. The firm‘s product results are comparable to that of the competitor product.</td></tr>
</table>

19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of Nebivolol HCl & Valsartan from 27-11-2017 to 13-09-2018 was submitted by the firm.

Remarks Of Evaluator:

Sr. No.	Query	Response by the form
1	Submit valid GMP Certificates of Both API Manufacturers, as these are not valid now.	When we submitted Registration file , GMP certificate of the manufacturer were valid then. Now we are again submitting valid GMP certificates.
2	Submit documents for the procurement of excipients Color Red # 40 & HPMC; used in manufacturing of trial batches.	documents for the procurement of excipients; Color Red # 40 & HPMC; used in manufacturing of trial batches are submitted now.
3	Sodium starch glycolate is not an excipient of innovator & you have not performed drug excipient compatibilities studies, How would you justify the compatibility of this excipient with drug.	Sodium Starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule & tablet formulations. It is commonly used in tablet prepared by either direct compression or wet granulation process. Although the effectiveness of many disintegrants is effected by the presence of hydrophobic excipients such as lubricants, the disintegrant efficiency of sodium stach glycolate is unimpaired. Ref: Hand book of Pharmaceutical Excipients, sixth edition.

Decision: Registration Board decided to approve registration of "Betanorm Plus Tablets 5/80mg (Nebivolol as hydrochloride & Valsartan) by M/s Werrick pharmaceuticals, Islamabad. 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 GMP Inspection Report Date & Remarks
947.	M/s Saffron Pharmaceuticals (Pvt.) LTD, 19 Km Sheikhupura Road, Faisalabad.	SAFPAVIR TABLET Each film coated tablet contains: Sofosbuvir…400 mg Velpatasvir**…**100 mg	Duplicate Dossier. Form-5D Dated.28-10-2016 Rs.50,000/- (Photocopy) Rs. 34500/28's	Approved in US-FDA. The firm was granted GMP certificate based on inspection conducted on dated 3rd of October, 2018.

STABILITY STUDY DATA

Drug	SAFPAVIR Tablet 400mg/100mg.
Name of Manufacturer	M/s Saffron Pharmaceuticals (Pvt.) LTD, 19 Km Sheikhupura Road, Faisalabad.
Manufacturer of API	**Sofosbuvir:** M/s Ruyuan HEC Pharm Co Ltd. China. **Velpatasvir:** M/s Ruyuan HEC Pharm Co Ltd. China.
API Lot No.	**Sofosbuvir:** YAK-RD201608202 **Velpatasvir:** VEPII-20162001
Description of Pack (Container closure system)	Alu/Alu blister packed in unit cartoon (28's)
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH

Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 3,6 (month) Real Time: 0, 3,6 (month)		
Batch No.	T-002	T-003	T-004
Batch Size	1500	1500	1500
Manufacturing Date	07-2017	09-2017	09-2017
Date of Initiation	07-2017	07-2017	09.2017
No. of Batches	03		
Date of Submission	22-02-2019 (Dy. No 22-02-19)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Firm has submitted copy of GMP certificate of **Sofosbuvir** of M/s Ruyuan HEC Pharm Co Ltd. China, Issued by Shaoguan Food and Drug Administration China dated 19.12.2018 Firm has submitted copy of GMP Certificate of **Velpatasvir** of M/s Ruyuan HEC Pharm Co Ltd. Issued by Shaoguan Food and Drug Administration China dated 19-12-2018.
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.	Firm has submitted following: Copy of GMP certificate for Sofosbuvir & Velpatasvir copovidone dispersion. Issued To: M/s Ruyuan HEC Pharm Co Ltd. China. Issued By: Shaoguan Food and Drug Administration China. Issued On: 19.12.2018. Valid up till: 18-12-2019
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:** □ Firm has submitted copy of ADC attested invoice confirming import of 5.0 Kg from The invoice was cleared on 15.01.2017. **Velpatasvir** □ Firm has submitted copy of ADC attested invoice confirming import of 1.80 Kg M/s Ruyuan HEC Pharm Co Ltd. China .The invoice was cleared on 06.04.2017.
6.	All provided documents will be attested (name, sign and	Yes

	stamp) for ensuring authenticity of data / documents.	
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

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 Saffaldi Tablet 400mg (Sofosbuvir), which was conducted on 8th January, 2018 and was presented in 279th meeting of Registration Board held on 28th of February -2nd of March, 2018. Following two observations were reported in the report: i. The HPLC software is 21CFR Compliant. ii. 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).	Applicant has submitted ADC attested invoice stating following information on it: **For Sofosbuvir:** Manufacturer of API: M/s Ruyuan HEC Pharm Co Ltd. China. Exporter of API: M/s. WIS Pharmatech, China. Quantity of API: 5Kg. Cleared on/Attested on: 15-01-2017. **For Velpatasvir Co-Povidone solid dispersion:** Manufacturer of API: M/s Ruyuan HEC Pharm Co Ltd. China. Exporter of API: M/s. WIS Pharmatech, China. Quantity of API: 5Kg. Cleared on/Attested on: 06-04-2017.
3.	Documents for the procurement of reference standard and impurity standards.	
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted following: Copy of GMP certificate for Sofosbuvir & Velpatasvir Co-Povidone Dispersion. Issued To: M/s Ruyuan HEC Pharm Co Ltd. China. Issued By: Shaoguan Food and Drug Administration China. Issued On: 19.12.2018. Valid up till: 18-12-2019.
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of SOPs for vendor qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards.	Firm has submitted following documents: COA of both APIs from M/s. Ruyuan HEC. Qualification report reference standard. Qualification report of Sofosbuvir impurity Standards A, B, C, D, F.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of technical staff of product development with relevant experience.

Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized general protocols/SOPs for the development & testing of trial batches.
10	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches.
11	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch T-002: 252 Tablets T-003: 430 Tablets T-004: 430 Tablets
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 of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
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 submitted method of analysis of FPP and complete record of testing of stability batches along with chromatograms
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted drug excipient compatibility studies by mixing both API with all excipients and then determination of % content by HPLC.
18.	Record of comparative dissolution data.	Firm has submitted data of comparative dissolution profile at pH 1.2, 4.5 and 6.8.and calculated values of f2 which were within accepted range
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trial reports for HPLC analysis for all the three batches.

Evaluation by PEC:

S.#	Query	Response by the firm
1.	Submit documents for the procurement of reference standard and impurity standard as in this section your have submitted commercial invoices for the import of API.	Chromatographic purity by HPLC (%age Area) documents are attached herewith. Therefore no impurity standard required in such case.
2.	COAs of reference standard and impurity standards have not been submitted.	COA of reference standard submitted
3.	Submit record of digital datat logger of stability chamber for accelerated stability studies.	Documents are submitted.
4.	Submit procedure for drug-excipient compatibilities studies.	Required stability data according to Zone IV-A manufacturer has not provided the data due to current Crisis between both the countries; we are continuously having follow up regarding this matter.
5.	Evidence of procurement of reference drug procedure for CDP.	Applicant has submitted something else

6.	For six month stability studies of Trial T003 all chromatograms for Velpatasvir have two peaks in them. Justify / clarify.	Single peak are visible, Documents are attached herewith
7.	For 3rd month stability studies of trial T002 peaks on chromatograms for both APIs are not visible. Clarify / justify.	PDA detector used in that case of two peaks.

Decision: Registration Board decided to approve registration of "SAFPAVIR Tablets 400mg/100mg (Sofobuvir & Velpatasvir) by M/s Saffron Pharmaceuticals (Pvt.) LTD, Faisalabad. 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.

948.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals, 387-388, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	CO-O Tablets 2.5mg
	Composition	Each film coated tablet contains: Apixaban……..2.5mg
	Diary No. Date of R& I & fee	Dy No. ; 06-12-2018: 20,000/- ; 07-12-18
	Pharmacological Group	Factor XA Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA Eliquis
	Me-too status	Apixa Tablets CCL Pharmaceuticals
	GMP status	GMP Inspection conducted on 24-01-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	CO-O Tablets 2.5mg		
Name of Manufacturer	M/s Wilson's Pharmaceuticals, 387-388, Industrial Area, Islamabad.		
Manufacturer of API	M/s Glenmark Pharmaceuticals, Ltd, GIDC Industrial Estate, Ankleshwar-393002, Gujarat State, India		
API Lot No.	Lot #: 801704823 , Quantity; 100g		
Description of Pack (Container closure system)	Alu /PVC Blister Pack in Unit carton		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Trial #01/Trial 01A	Trial #02	Trial #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	18-03-2018	19-03-2018	20-03-2018
No. of Batches	03		
Date of Submission	(06-12-2018)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (batch #801704823) from M/s Glenmark

		Pharmaceuticals, Ltd, Plot no 3109, GIDC Industrial Estate, Ankleshwar- 393002, and Gujarat State, 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 (certificate No. G/25/1629) issued by Food & Drugs Control Administration, India. It is valid until 30-04-2020.
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.	The firm has submitted copy of commercial invoice for 100gm dated 29-09-2017 attested by ADC, 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 firm has submitted 6months Accelerated and 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 following documents as per checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 27-02-2018 vide diary No. 8825.

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 "Saferon (Sofosbuvir 400mg) Tablets", which was conducted on 19th April, 2017 and was presented in 278th meeting of Registration board. Registration Board decided to approve registration of Saferon (Sofosbuvir 400mg) Tablets" by M/s. Wilson Pharmaceuticals Islamabad. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. • The firm possesses stability chambers with digital data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice dated 29-09-2017 attested by ADC, DRAP, Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of invoice declaring following information: For Working Standard & Impurities A, B, C, D, E. Invoice Number : 2006007417 Dated: 05-12-2017
4.	Approval of API/ DML/GMP certificate of API manufacturer issued	The firm has submitted copy of GMP certificate declaring following information:

<table>
<tr><td></td><td>by regulatory authority of country of origin.</td><td>Certificate No. G/25/1629
Issued to: M/s Glenmark Pharmaceuticals, Ltd, Plot No. 3109, GIDC Industrial Estate, Ankleshwar- 393002, Gujarat State, India
Issued by: Food & Drugs Control Administration, Gujrat state India.
Validity: Valid Till 18-08-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Applicant has submitted following COAs:
<u>For API:</u>
Copy of COA (batch #801704823) from M/s Glenmark Pharmaceuticals, Ltd, Plot No. 3109, GIDC Industrial Estate, Ankleshwar- 393002, Gujarat State, India is submitted.
<u>For reference/working standard:</u>
Copy of COA of working standard for is submitted.
Working standard Number: 18801-01.
<u>For Impurities:</u>
Copy of COA of impurity Standards A, B, C, D & E 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 all 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 comprising of 11 members 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 CO-O Tablets 2.5 mg”.</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>03-2018</td></tr><tr><td>Trial # 02</td><td>1500 tablets</td><td>03-2018</td></tr><tr><td>Trial # 03</td><td>1500 tablets</td><td>03-2018</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 rowspan="2">Trial No</th><th colspan="2">CO-O Tablets 2.5mg
Remaining Quantity</th></tr><tr><th>Accelerated</th><th>Long Term</th></tr><tr><td>Trial # 01</td><td>109 tablets</td><td>205 tablets</td></tr><tr><td>Trial # 02</td><td>109 tablets</td><td>205 tablets</td></tr><tr><td>Trial # 03</td><td>109 tablets</td><td>205 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 data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopies of following:
Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house).
COAs for Apixaban (Supplier/Manufacturer).</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability</td><td>The firm has submitted photocopies of following:
FPP Test/Analysis Method & FPP Specifications (In-house)</td></tr>
</table>

	batches (i.e. chromatograms, lab reports, raw data sheets etc.)	for CO-O Tablets 2.5 mg.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Apixaban from M/s Glenmark Pharmaceuticals, Ltd, India.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Excipients of applied drug product are similar to that of innovator product (Eliquis).
18.	Record of comparative dissolution data.	The firm has submitted comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Sodium Phosphate Buffer) pH 6.8 buffers with Eliquis Tablets 5mg manufactured by Pfizer Ortakoy with Batch No.171731108.
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.

Remarks of Evaluator:

S. NO.	Query	Response by the firm.
1	In procedure for dissolution testing it is mentioned that measure the other absorbance on UV spectrometer at 277±5nm. Clarify / justify	Submitted spectra of dissolution test show absorbance by peak pick calculation. A spectrophotometer records the degree of absorption by a sample at different wavelength and the resulting plot of absorbance (A) versus (λ) is known as a spectrum. By peak pick calculation spectrophotometer give absorbance at λ max (wavelength at which there is a maximum absorbance). That is why there is ± difference from actual wavelength is observed. Now spectra of next two intervals (9^{th} month & 12 Month) with point pick calculation of absorbance at single & fix wavelength of Apixaban are attached. All result of dissolution test are within limit.
2	Result of dissolution testing is calculated without considering the potency of standard as the potency of working standard is 99%. Clarify / justify	On certificate of analysis of working standard, assay limit is 98-102% while potency of working standard is 99.1% as per COA,that complies with assay limit. If we are getting such assay result of working standard like 99% or 101% we can consider it analytical deviation and can round it to 100% for routine application or can use potency as 100%. If assay results of working standard are not within limit then it is very necessary to confirm the things with high degree of investigation.
3	Why the content uniformity test is not performed by the firm, Clarify / justify.	Content uniformity test had been performed but was not submitted as it is not a stability indicating parameter. Content uniformity data, attached as Now.
4	Submit how much quantity of working standards and impurities are imported airway bill/any other evidence for the import of the same.	Working standard & all impurities are supplied by supplier, free of cost and on our demand non commercial invoice & COAs of working standard and all impurities is provided by supplier, attached now.
5	Submit invoice for purchase of SLS and lactose (Tablettose)	We are submitting it Now.
6	Submit evidence of purchase of reference product/innovator product.	Firm has submitted photocopy of pictures of outer packing of reference pro reference product/innovator product.
7	Chromatograms of method validation studies are verifiable from submitted audit trail data. Justify / clarify	We are submitting it Now.

Decision: Registration Board deferred the case & advised the firm to mention that one wavelength (ƛ max wavelength at which there is a maximum absorbance) at which dissolution testing has to be performed & submit the results of dissolution testing for next time interval by taking reading on that wavelength(ƛ max).

949.	Name and address of manufacturer / Applicant	M/s Wilson's Pharmaceuticals, 387-388, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	CO-O Tablets 5mg
	Composition	Each film coated tablet contains: Apixaban……..5mg
	Diary No. Date of R& I & fee	Dy No. ; 06-12-2018: 20,000/- ; 07-12-18
	Pharmacological Group	Factor XA Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA Eliquis
	Me-too status	Apixa Tablets CCL Pharmaceuticals
	GMP status	GMP Inspection conducted on 24-01-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	CO-O Tablets 5mg		
Name of Manufacturer	M/s Wilson's Pharmaceuticals, 387-388, Industrial Area, Islamabad.		
Manufacturer of API	M/s Glenmark Pharmaceuticals, Ltd, GIDC Industrial Estate, Ankleshwar-393002, Gujarat State, India		
API Lot No.	Lot #: 801704823 , Quantity; 100g		
Description of Pack (Container closure system)	Alu /PVC Blister Pack in Unit carton		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Trial #01	Trial #02	Trial #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	21-03-2018	22-03-2018	23-03-2018
No. of Batches	03		
Date of Submission	(06-12-2018)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (batch #801704823) from M/s Glenmark Pharmaceuticals, Ltd, Plot no 3109, GIDC Industrial Estate, Ankleshwar- 393002, Gujarat State, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory	Copy of GMP certificate (certificate No. G/25/1629) issued by Food & Drugs Control Administration, India. It is valid until 30-04-2020.

	authority of country of origin.	
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 dated 29-09-2017 attested by ADC, 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 firm has submitted 6months Accelerated and 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: 27-02-2018 vide diary no.

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 "Saferon (Sofosbuvir 400mg) Tablets", which was conducted on 19th April, 2017 and was presented in 278th meeting of Registration board. Registration Board decided to approve registration of Saferon (Sofosbuvir 400mg) Tablets" by M/s. Wilson Pharmaceuticals Islamabad. According to the report following points were confirmed. • The firm has 21 CFR compliant HPLC software • The firm has audit trail reports available. The firm possesses stability chambers with digital data loggers.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice dated 19th of September 2017 declaring 100g quantity of API has been submitted which is attested by ADC, DRAP Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of commercial invoice dated 29-09-2017 attested by ADC, DRAP, Islamabad. The firm has submitted copy of invoice declaring following information: For Working Standard & Impurities A, B, C, D, E. Invoice Number : 2006007417 Dated: 05-12-2017
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 declaring following information: **Certificate No**. G/25/1629 **Issued to**: M/s Glenmark Pharmaceuticals, Ltd, Plot no 3109, GIDC Industrial Estate, Ankleshwar- 393002, Gujarat State, India **Issued by**: Food & Drugs Control Administration, India.

<table>
<tr><td></td><td></td><td>Validity: Valid Till 18-008-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
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<u>For API:</u>
• Copy of COA (batch #801704823) from M/s Glenmark Pharmaceuticals, Ltd, Plot No. 3109, GIDC Industrial Estate, Ankleshwar- 393002, Gujarat State, India is submitted.
<u>For reference/working standard:</u>
• Copy of COA of working standard for is submitted.
Working standard Number: 18801-01.
<u>For Impurities:</u>
Copy of COA of impurity Standards A, B, C, D & E has been submitted.</td></tr>
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<tr><th rowspan="2">Trial No</th><th colspan="2">CO-O Tablets 5mg
Remaining Quantity</th></tr>
<tr><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>Trial # 01</td><td>109 tablets</td><td>205 tablets</td></tr>
<tr><td>Trial # 02</td><td>109 tablets</td><td>205 tablets</td></tr>
<tr><td>Trial # 03</td><td>109 tablets</td><td>205 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 data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-03-2018 to 30-09-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopies of following:
• Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house).
• COAs for Apixaban (Supplier/Manufacturer).</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 photocopies of following:
• FPP Test/Analysis Method & FPP Specifications (In-house) for CO-O Tablets 5 mg.</td></tr>
</table>

15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 36 Months Real Time Stability Study Data of 03 Batches of Apixaban from M/s Glenmark Pharmaceuticals, Ltd, India.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	Excipients of applied drug product are similar to that of innovator product (Eliquis).
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies in three media including (0.1 N HCl) pH 1.2, (Acetate Buffer) pH 4.5 and (Sodium Phosphate Buffer) pH 6.8 buffers with Eliquis Tablets 2.5mg manufactured by Pfizer Ortakoy with Batch No.171731002R..
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.

Remarks of Evaluator:

S. NO.	Query	Response by the firm.
1	In procedure for dissolution testing it is mentioned that measure the other absorbance on UV spectrometer at 277±5nm. Clarify / justify	Submitted spectra of dissolution test show absorbance by peak pick calculation. A spectrophotometer records the degree of absorption by a sample at different wavelength and the resulting plot of absorbance (A) versus (λ) is known as a spectrum. By peak pick calculation spectrophotometer give absorbance at λ max (wavelength at which there is a maximum absorbance). That is why there is ± difference from actual wavelength is observed. Now spectra of next two intervals (9th month & 12 Month) with point pick calculation of absorbance at single & fix wavelength of Apixaban are attached. All result of dissolution test are within limit.
2	Result of dissolution testing is calculated without considering the potency of standard as the potency of working standard is 99%. Clarify / justify	On certificate of analysis of working standard, assay limit is 98-102% while potency of working standard is 99.1% as per COA,that complies with assay limit. If we are getting such assay result of working standard like 99% or 101% we can consider it analytical deviation and can round it to 100% for routine application or can use potency as 100%. If assay results of working standard are not within limit then it is very necessary to confirm the things with high degree of investigation.
3	Why the content uniformity test is not performed by the firm, Clarify / justify.	Content uniformity test had been performed but was not submitted as it is not a stability indicating parameter. Content uniformity data, attached as Now.
4	Submit how much quantity of working standards and impurities are imported airway bill/any other evidence for the import of the same.	Working standard & all impurities are supplied by supplier, free of cost and on our demand non commercial invoice & COAs of working standard and all impurities is provided by supplier, attached now.
5	Submit invoice for purchase of SLS and lactose (Tablettose)	We are submitting it Now.
6	Batch numbers of two trial batches of both strengths of applied drug product are similar. How would you have distinguished them during stability studies?	ON each pack and strip of all three trials of both strength of Apixabantablets, there is in houise printing ofBrand Name with composition. Trial # Mfg. Date & expiry date and tablet color both strength is also different (light yellow color 2.5mg

			tablet & orange color 5mg tablet. Therefor all three trials can be easily distinguished / identified during stability study.
	7	Chromatograms of method validation studies are verifiable from submitted audit trail data. Justify / clarify	We are submitting it Now.
Decision: Registration Board deferred the case & advised the firm to mention that one wavelength (ƛ max wavelength at which there is a maximum absorbance) at which dissolution testing has to be performed & submit the results of dissolution testing for next time interval by taking reading on that wavelength(ƛ max).			

Evaluator PEC-VII

Case No. 01 Registration Applications for Local Manufacturing of (Human) Drugs.

a. New cases

950.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products Pvt Ltd, D-122, S.I.T.E, Karachi
	Brand Name +Dosage Form + Strength	Quesanic 100 mg tablets
	Composition	Each Film coated tablet contains: Quetiapine (as Fumarate)……..100mg
	Diary No. Date of R& I & fee	Dyn# 11237, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel 100 mg film-coated tablets Approved in MHRA as film-coated
	Me-too status	Pequit tablets of M/s Medizan Pharmaceuticals
	GMP status	Copy of inspection conducted on 5-6-2018 and the report concludes that firm overall ratings is GOOD.
	Remarks of Evaluator	
	Decision: Approved.	
951.	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+DosageForm+Strength	Ponstapharm Forte Tablet 500mg
	Composition	Each Film coated tablet contains: Mefenamic Acid….500mg
	Diary No. Date of R&I & fee	Dy.No.2707, 26-01-2017, Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	B.P
	Pack Size & Demanded Price	100's,200's,300'S; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ponstan Forte Tablets by Chemidex Pharma Ltd UK
	Me-too status	DOLORAN-DS Tablet by EPLA Pharma
	GMP status	Last Inspection report conducted on 27-04-2017 and panel is of the view to grant GMP certificate
	Remarks of Evaluator	
	Decision: Approved.	
952.	Name and address of Manufacturer / Applicant	M/S Epharm Laboratories, A-40, Road No.1, S.I.T.E, Super Highway, Industrial Area, ephagNorth Karachi, Pakistan.
	Brand Name+DosageForm+Strength	Ephagesic Tablets 450mg/35mg
	Composition	Each uncoated tablet contains: Paracetamol….450mg Orphenadrine citrate……35mg

	Diary No. Date of R&I & fee	Dy.No.2708, 26-01-2017, Rs.20,000/-
	Pharmacological Group	Analgesic & Skeletal muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	50's,100's,500'S; As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic by M/s iNova Pharmaceuticals, Australia (TGA)
	Me-too status	Acetor of Neomedix
	GMP status	Last Inspection report conducted on 27-04-2017 and panel is of the view to grant GMP certificate
	Remarks of Evaluator	
	Decision: Approved.	
953.	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+DosageForm+Strength	Ephamic -250mg Injection IM/IV
	Composition	Each 5ml contains: Tranexamic Acid…..250mg
	Diary No. Date of R&I & fee	Dy.No.1176, 11-01-2017, Rs.20,000/-
	Pharmacological Group	Haemostatic/Fibrinolytic
	Type of Form	Form-5
	Finished Product Specification	B.P
	Pack Size & Demanded Price	5mlx1's,5mlx5's,5mlx10's,5mlx100's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Tranexamic Acid-250mg/5ml Injection by Advacare Pharma USA
	Me-too status	BRINO-250mg injection by SAMI PHARMA.
	GMP status	Last Inspection report conducted on 27-04-2017 and report concludes that the overall GMP was satisfactory.
	Remarks of Evaluator	
	Decision: Approved.	
954.	Name and address of manufacturer / Applicant	M/s Cherwel Pharmaceuticals (Pvt) Ltd Plot # 20, phase 4, Hattar industrial estate, KPK Pakistan
	Brand Name +Dosage Form + Strength	Esocure 20mg Capsule
	Diary No. Date of R& I & fee	Form-5 Dy.No 22895 dated 04-12-2017 Rs. 20,000/- DATED 04-12-2017
	Composition	Each Capsule Contains: Esomeprazole (enteric coated pellets)…20mg
	Pharmacological Group	Antacid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Esomeprazole 20 mg Capsule by Generics UK (MHRA Approved)
	Me-too Status	Nexum Capsule by Getz Pharma
	GMP status	Last GMP inspection was conducted on 4-2-2019 and panel recommend the renewal of DML
	Remarks of the Evaluator.	Source of pellets: M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved.	
955.	Name and address of manufacturer / Applicant	M/s Cherwel Pharmaceuticals (Pvt) Ltd Plot # 20, phase 4, Hattar industrial estate, KPK Pakistan
	Brand Name +Dosage Form + Strength	Nafzole 40 mg
	Diary No. Date of R& I & fee	Form-5 Dy.No 22896 dated 04-12-2017 Rs. 20,000/- Dated 04-12-2017
	Composition	Each capsule contains: Omeprazole (as 22.5%w/w enteric coated pellets) …….. 40mg
	Pharmacological Group	Antacid
	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
	Me-too Status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	Last GMP inspection was conducted on 4-2-2019 and panel recommend the renewal of DML
	Remarks of the Evaluator.	Source of pellets: M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved.	
956.	**Name and address of manufacturer / Applicant**	M/s ICI Pharmaceuticals 5, West wharf, Karachi Contract manufacture by Nabiqasim industry 17/24, Korangi industrial area Karachi
	Brand Name +Dosage Form + Strength	Etipro IV infusion
	Diary No. Date of R& I & fee	Dy.No. Duplication 30-Aug-2016, 50,000/- (duplicate)
	Composition	Each Vial Contains:- Omeprazole (as Sodium) …… 40 mg
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished Product Specification	As per innovator
	Pack size & Demanded Price	1's / As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV of sandoz (TGA)
	Me-too status	Loprot of Nabiqasim
	GMP status	Last GMP Inspection dated 3-08-2017 with conclusive remarks of acceptable cGMP compliance
	Remarks of the Evaluator.	• No USP or BP monograph is available for applied formulation. • ICI has 2 sections • They are already manufacturing 6 products on contract manufacturing bases.
	Decision: Deferred whether application was submitted by M/s ICI or Wyeth.	
957.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals, 36, industrial area triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Clorten 4 mg tablets
	Composition	Each film-coated tablet contains: Lornoxicam ….4mg
	Diary No. Date of R& I & fee	Dyn# 11259, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	1x10'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	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP status	Last inspection report 16 jan 2019, Firm is allowed to start the manufacturing in the light of GMP guideline
	Remarks of Evaluator	
	Decision:Approved with innovator's specification.	
958.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals, 36, industrial area triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amval tablet 10/160
	Composition	Each film coated tablet contains: Amlodipine (as besylate)….. 10 mg

		Valsartan…..160mg
	Diary No. Date of R& I & fee	Dyn# 11259, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's / As per SRO
	Approval status of product in Reference Regulatory Authorities	EXFORGE of USFDA
	Me-too status	Amlodine Tablet 10/160mg of M/s Jupiter Pharma
	GMP status	Last inspection report 16 jan 2019, Firm is allowed to start the manufacturing in the light of GMP guideline
	Remarks of Evaluator	
	Decision:Approved.	
959.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals, 36, industrial area triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amval tablet 5/80
	Composition	Each film coated tablet contains: Amlodipine (as besylate)….. 5 mg Valsartan…..80 mg
	Diary No. Date of R& I & fee	Dyn# 11256, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Amlodine Tablet 5/80 mg of M/s Jupiter Pharma
	GMP status	Last inspection report 16 jan 2019, Firm is allowed to start the manufacturing in the light of GMP guideline
	Remarks of Evaluator	
	Decision:Approved.	
960.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals, 36, industrial area triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Amval tablet 5/160
	Composition	Each film coated tablet contains: Amlodipine (as besylate)….. 5 mg Valsartan…..160mg
	Diary No. Date of R& I & fee	Dyn# 11257, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Amlodine Tablet 5/160 mg of M/s Jupiter Pharma
	GMP status	Last inspection report 16 jan 2019, Firm is allowed to start the manufacturing in the light of GMP guideline
	Remarks of Evaluator	
	Decision:Approved.	
961.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals, 36, industrial area triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Azolin 400mg tablets
	Composition	Each film coated tablet contains: Doxyphylline ….. 400 mg

	Diary No. Date of R& I & fee	Dyn# 11260, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	Anti-Asthmatic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x10's / As per SRO
	Approval status of product in Reference Regulatory Authorities	NA (In Italy)
	Me-too status	Doxfree of EG Pharma
	GMP status	Last inspection report 16 jan 2019, Firm is allowed to start the manufacturing in the light of GMP guideline
	Remarks of Evaluator	
	Decision:Approved.	
962.	Name and address of manufacturer / Applicant	M/s Paramount Pharmaceuticals, 36, industrial area triangle Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Azolin 8 mg tablets
	Composition	Each film-coated tablet contains: Lornoxicam ….8mg
	Diary No. Date of R& I & fee	Dyn# 11258, 7-8-2017, Rs, 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specs
	Pack size & Demanded Price	1x10's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved)
	Me-too status	Acabel 8mg Tablet by M/s Continental Pharma
	GMP status	Last inspection report 16 jan 2019, Firm is allowed to start the manufacturing in the light of GMP guideline
	Remarks of Evaluator	
	Decision:Approved with innovator's specification.	

b. DEFERRED CASES

963.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals, 126-B, Industrial estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Ketrowin 30 mg/ ml injection
	Composition	Each ampoule contains:- Ketorolac tromethamine as ketorolac…… 30 mg
	Diary No. Date of R& I & fee	Dy. No. 297; 8-8-2016; Rs. 20,000/-
	Pharmacological Group	Anti-inflammatory and anti-rheumatic products
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	1x1 ampoule: As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketorolac Tromethamine Injection 30mg/ml by M/s Hospira Pharmaceuticals, USFDA approved
	Me-too status	Toralac Injection 30mg/ml by M/s Vision Pharmaceuticals
	GMP status	Last GMP Inspection conducted on dated 30-01-2018 with conclusive remarks of good cGMP compliance.
	Remarks of Evaluator	**Decision of 284:** Deferred for clarification of applied composition **Remarks of evaluator:** Revised form 5 for ketorolac to methamine 30 mg/ml was provide without fee. **Decision of 287:** Deferred for submission of fee for revision of formulation.
	Remarks of Evaluator:	Revised form 5 as per innovator is provided. Each ampoule contains:-

		Ketorolac tromethamine …… 30 mg was provide with fee of 5000/- (Fee challan 0803231) dated 18/5/2019
	Decision:Approved.	
964.	Name and address of manufacturer / Applicant	M/s Dr Raza Pharma,44-C, industrial estate Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Lansozol 30 mg capsules
	Composition	Each capsule contains: Lansoprazole (as enteric-coated 8.5% pellets)……30 mg
	Diary No. Date of R& I & fee	Dy.No. 3095, 30-4-2015, Rs.12,000/- (13-01-15), Rs.8000/-, (4-March- 2011)
	Pharmacological Group	Anti-Peptic Ulcerant, 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.	Lansoprazole 30mg GR capsules of M/s Generics limited (UK MHRA Approved)
	Me-too status	Inhibitol capsules 30mg of M/s Highnoon Laboratories
	GMP status	Last GMP Inspection conducted on 18.03.2017 with conclusive remarks of cGMP.
	Remarks of Evaluator	Source of pellets Vision pharma. Latest GMP
	Decision of 283: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **Remarks of evaluator:** Last GMP Inspection conducted on 24-June 2019 with conclusive remarks of satisfactory cGMP.	
	Decision: Approved.	
965.	Name and address of manufacturer / Applicant	M/s Noa Hemis Plot #154, Sector 23, Korangi industrial area Karachi
	Brand Name +Dosage Form + Strength	Bianchi Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloirde……5 mg
	Diary No. Date of R& I & fee	Dy.No. 1569, 4-8-2016, Rs.20,000/-
	Pharmacological Group	Anti-Histaminic
	Type of Form	Form-5
	Finished Product Specification	Innovators
	Pack size & Demanded Price	60 ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Letirix Syrup of M/s Alliance Pharmaceuticals
	GMP status	Last GMP Inspection dated 17-11-16 with conclusive remarks of cGMP compliance
	Remarks of Evaluator	Levocetirizine dihydrochloride 2.5mg/5ml oral solution is available in USFDA
	Decision of 274: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. **Remarks of evaluator:** Revised dossier is provided as under	
	Revised Dossier;	
	Name and address of manufacturer / Applicant	M/s Noa Hemis Plot #154, Sector 23, Korangi industrial area Karachi
	Brand Name +Dosage Form + Strength	Bianchi Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloirde……2.5 mg
	Diary No. Date of R& I & fee	Dy.No. 7719, 21-2-2019, Rs. 5000/- (Challan # 0545425)

	Pharmacological Group	Anti-Histamin/Antiallergic
	Type of Form	Form-5
	Finished Product Specification	Innovators
	Pack size & Demanded Price	60 ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xyzal 0.5mg/ml oral solution of M/s UCB Pharma Limited (MHRA Approved)
	Me-too status	Ocitra Syrup of M/s Searle Pakistan (Pvt.) Limited (Reg. #054519)
	GMP status	Last GMP Inspection dated 28-2-2019 with panel recommend grant of DML renewal
	Remarks of Evaluator	
	Decision: Deferred for submission of requisite fee for the revision of formulation.	

Case No. 02: Registration Applications of Newly Granted DML or New Section (Human).

c. Deferred Cases New DML/New Section(s)

966.

Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad

M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad
In response to licensing division letter dated 04-September, 2018 has considered the grant of following new sections. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

Sr. No	Section	No. of products	No. of molecules
1	Sterile Dry powder vials section (Steroid)		
2	Sterile liquid ampoule section (Steroid)		
3	Topical section (Steroid)		
4	Eye/ear/Nose drops section (Steroid)		
5	Warehouse (Steroid)		
6	Sterile liquid Vial SVP section (General)	11	10
7	Liquid ampoule SVP section (General)		

Brand Name +Dosage Form + Strength	Tirostat 12.50mg/50ml Injection
Diary No. Date of R& I & fee	Form-5 Dy.No 40226 dated 05-12-2018 Rs.20,000/- Dated 05-12-2018
Composition	Each 50ml Injection Contains: Tirofiban as Hydrochloride Monohydrate…12.5mg
Pharmacological Group	Platelet aggregation inhibitors excl. heparin
Type of Form	Form-5
Finished Product Specification	In-house Specification
Pack size & Demanded Price	100ml's, As per SRO
Approval status of product in Reference Regulatory Authorities.	Aggrastat 250 mcg/ml concentrate for solution for infusion in 50 ml Type I glass vial. (MHRA Approved)
Me-too status	Aggrastat of atco laboratories limited
GMP status	New section: 19 Sep 2018
Remarks of Evaluator	

Decision of 283: Deferred for evidence of approval of applied formulation with 100ml fill volume in reference regulatory authorities which were adopted by Registration Board in its 275th meeting is required.
Remarks of evaluator:
The firm provide the copy of form 5 in which the applied volume is 50 mlwhich is in accordance with reference product present in reference regulatory authority (MHRA) which were adopted by Registration Board in its 275th meeting is required.

Decision:Approved with innovator's specification.

967.

Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot # 31& 32 Punjab Small Industrial Estate Taxila
Brand Name +Dosage Form + Strength	Wemsin 0.4 mg capsule

	Diary No. Date of R& I & fee	Form-5 Dy.No 26462 (28-12-2012) Rs. 20,000/- 28-12-2017
	Composition	Each capsule contains: Tamsulosin HCl 0.2% pellets…….0.4mg
	Pharmacological Group	Antivertigo preparations
	Type of Form	Form-5
	Finished Product Specification	Innovators
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Tamsulosin Zentiva 400 microgram prolonged-release hard capsules (MHRA approved)
	Me-too Status	Talsin of Pharmedic (Pvt) Ltd
	GMP status	Last GMP inspection conducted on 29-10-2018, and the report concluded that there is some need of improvement which have been discussed and agreed. Panel recommend the grant of GMP certificate.
	Remarks of the Evaluator.	In form 5 the strength of tamsulosin is different from strength throughout dossier. Form 5 is revised by the firm without fee
	Decision of 287: Deferred for clarification of applied composition along with submission of fee for revision of Form 5. **Remarks of Evaluator:** Revised form 5 as per innovator (MHRA approved) is provided. Each modified release capsule contains: Tamsulosin HCl …….0.4mg (as modified released pellets) Fee of 5000/- (Fee challan 01917517) dated 09/04/2019 is provided	
	Decision: Deferred for COA, GMP of pellet manufacturer along with stability studies data both accelerated & real time conducted in accordance with zone IV-A conditions, and differential fee in case of import of pellets.	
968.	Name and address of Manufacturer / Applicant	M/s Liven pharmaceuticals 49, km, Multan road Lahore
	Brand Name+ Dosage Form+ Strength	Vit-B 3 ml injection. IM/IV
	Composition	Each ml Contains: B1 (Thiamine HCL)…33.33mg B6 (Pyridoxine HCL)…33.33mg B12 (Cyanocobalamin)…33.33mg
	Diary No. Date of R&I & fee	Dy No. 17338 ; 10-05-2018; Rs.20,000/- Dated 10-05-2018
	Pharmacological Group	Multivitamin
	Type of Form	Form-5
	Finished Product Specification	Innovators
	Pack Size & Demanded Price	3 ml, 5's, 10's, 25's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Neurobion ampoules by M/s Merck (Germany Approved)
	Me-too status	Bevidox 3ml Injection by M/s Abbott (Reg#008345)
	GMP status	New DML
	Remarks of Evaluator	The formulation's composition mentioned on Form 5 and Master formulation is different which need clarification.
	Decision of 285: Deferred for evidence of approval of applied formulation in reference regulatory authority adopted by Registration Board in 275th meeting. **Remarks of evaluator** [VII] Revised formulation is submitted Each 3 ml Contains: B1 (Thiamine HCL)…100 mg B6 (Pyridoxine HCL)…100 mg B12 (Cyanocobalamin)…1000 mcg Fee of 20,000/- is provided (Deposit # 0817429, date: 01-02-2019)	
	Decision: Approved.	

Case. No.1. M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore (Additional section)

CLB in its meeting held on 2 March, 2018 has considered and renew the grant of drug manufacturing license by way of formulation with grant to following additional sections

Accordingly, firm has applied for following products for consideration by Drug Registration Board.

Sr. No	Section	No. of products	No. of molecules
1	Liquid repacking section (human)		
2	Powder repacking section (human)		
3	Sachet section (General) for human		
4	External preparations/ Application/Aerosol section for human		
5	Liquid injectable section (steroid) veterinary		
6	Oral Powder section (penicillin) veterinary		

External section:

969.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Oxy-G Plus Spray (vet)
	Diary No. Date of R& I & fee	Form-5 Dy.No 30859-B dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Composition	Each gm Contains: Oxytetracycline HCl…40mg Gentian violet…4mg Citronella oil…….20 mg Permethrine…….10 mg
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	Price: 435/125 ml 700/200ml
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TERAGEN Plus AEROSOL SPRAY
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	
	Decision 287: Deferred for justification of applied dosage form in the section of "Oral Powder section (Penicillin) Veterinary" **Remarks:** Firm inform that the applied formulation is under spray section newly approved by central licensing board. Letter of CLB is not attached	
	Decision:Deferred for review of formulation & its drug delivery system as applied formulation is spray & its ingredients are mentioned in grams.	
970.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Oxy-G Spray (Vet)
	Diary No. Date of R& I & fee	Form-5 Dy.No 30859-C dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Composition	Each gm Contains: Oxytetracycline HCl…40mg Gentian violet…4mg
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Manufacturer

	Pack size & Demanded Price	410/200 ml 256/125 ml 308/150ml
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TERAGEN AEROSOL SPRAY
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	•In cover letter it was mentioned that you are applying for human drug, but on form 5 the price of the applied formulation was claimed as decontrolled, which is claimed only for veterinary product. Clarify.
	Decision 287: Deferred for justification of applied dosage form in the section of "Oral Powder section (Penicillin) Veterinary" **Remarks:** Firm inform that the applied formulation is under spray section newly approved by central licensing board. Letter of CLB is not attached	
	Decision:Deferred for review of formulation & its drug delivery system as applied formulation is spray & its ingredients are mentioned in grams.	

Case no. 03 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

971.	Name and address of Manufacturer / Applicant	M/s Prix Pharmaceutical (Pvt) Ltd., Plot #5, pharma city, 30 km, Multan road, Lahore.
	Brand Name+ Dosage Form+ Strength	Pri-Trichlor 100 water soluble powder
	Composition	Each g contains:- Trichlorfon……..980 mg
	Diary No. Date of R&I & fee	Dy No. 5878 ; 13-06-2018; Rs.20,000/-
	Pharmacological Group	Organophosphate acetylcholinesterase inhibitor.
	Type of Form	Form-5
	Finished Product Specification	Innovators
	Pack Size & Demanded Price	100gm, 500 gm, 1000 gm. Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Seguvan Powdercontains, Trichlorphon 98% w/w of Symans Pharma
	GMP status	Latest GMP inspection report dated 11-12-2018 concluding renewal of grant of DML
	Remarks of Evaluator	
	Decision:Approved.	
972.	Name and address of Manufacturer / Applicant	M/s Prix Pharmaceutical (Pvt) Ltd., Plot #5, pharma city, 30 km, Multan road, Lahore.
	Brand Name+ Dosage Form+ Strength	Amanta-Pri 10% oral liquid
	Composition	Each 100 ml oral liquid contains:- Amantadine Hydrochloride……..100 g
	Diary No. Date of R&I & fee	Dy No.2714 ; 5-05-2017; Rs.20,000/-
	Pharmacological Group	DOPAMINERGIC AGENTS
	Type of Form	Form-5
	Finished Product Specification	USP (oral Solution)

	Pack Size & Demanded Price	100 ml, 250ml, 500 ml, 1000ml. Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	NA
	GMP status	Latest GMP inspection report dated 11-12-2018 concluding renewal of grant of DML
	Remarks of Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) can't be verified
	Decision:Deferred for the following: **For evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **For Clarification regarding difference in label claim & composition.**	
973.	Name and address of Manufacturer / Applicant	M/s Prix Pharmaceutical (Pvt) Ltd., Plot #5, pharma city, 30 km, Multan road, Lahore.
	Brand Name+ Dosage Form+ Strength	Ketoflame 10 injection
	Composition	Each ml contains:- Ketoprofen……...100 mg
	Diary No. Date of R&I & fee	Dy No.3811 ; 19-04-2017; Rs.20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100 ml glass vial Decontrolled
	Approval status of product in Reference Regulatory Authorities	Comforion Vet 100 mg/ml Solution for Injection of Orion Corporation, Finland (UK)
	Me-too status	Ketoject Injection of M/s Selmore Pharma (Reg # 043141)
	GMP status	Latest GMP inspection report dated 11-12-2018 concluding renewal of grant of DML
	Remarks of Evaluator	
	Decision:Approved with innovator's specification.	
974.	Name and address of Manufacturer / Applicant	M/s Prix Pharmaceutical (Pvt) Ltd., Plot #5, pharma city, 30 km, Multan road, Lahore.
	Brand Name+ Dosage Form+ Strength	Trocid 34 injection
	Composition	Each ml contains:- Nitroxynil……...340 mg
	Diary No. Date of R&I & fee	Dy No.2532 ; 10-04-2017; Rs.20,000/-
	Pharmacological Group	Dewormer/Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100 ml glass vial Decontrolled
	Approval status of product in Reference Regulatory Authorities	Trodax 34% w/v solution for injection by Merial Animal Health Limited, UK
	Me-too status	Nitroxy injection of Alina Combine Pharma (Reg # 049683)
	GMP status	Latest GMP inspection report dated 11-12-2018 concluding renewal of grant of DML
	Remarks of Evaluator	
	Decision:Approved with innovator's specification.	

975.	Name and address of Manufacturer / Applicant	M/s Prix Pharmaceutical (Pvt) Ltd., Plot #5, pharma city, 30 km, Multan road, Lahore.
	Brand Name+ Dosage Form+ Strength	Atropri-injection
	Composition	Each ml contains:- Atropine sulphate……..1 mg
	Diary No. Date of R&I & fee	Dy No.3375 ; 14-04-2017; Rs.20,000/-
	Pharmacological Group	Antimuscrinic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100 ml in glass vial Decontrolled
	Approval status of product in Reference Regulatory Authorities	NA
	Me-too status	Atrovet Injection. 1mg/ml By Selmore Pharmaceuticals, Lahore
	GMP status	Latest GMP inspection report dated 11-12-2018 concluding renewal of grant of DML
	Remarks of Evaluator	
	Decision:Approved with Japanese Pharmacopoeia Specifications.	

b. Deferred Cases

Section: Oral Powder section (penicillin) veterinary		
976.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-Amamox 80 gm Powder (Vet)
	Diary No. Date of R& I & fee	Form-5 Dy.No 31031-B dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Composition	Each 100gm Contains: Amoxicillin as Trihydrate…80 gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	100gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 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 December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	PRIMOX 70% WATER SOLUBLE POWDER of Prix can't be verified
	Decision 287: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Remarks:** Firm revised the form 5 along with fee of 5000/- (0807341) Each 100gm Water Soluble Powder Contains:- Amoxicillin Trihydrate …….80g Equivalent To 70g Of Amoxicillin Base **Me too** is confirmed. PRIMOX 70% WATER SOLUBLE POWDER ('074032)	
	Decision:Approved with innovator's specification.	
977.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-Amoxical DS Powder
	Diary No. Date of R& I & fee	Form-5 Dy.No 31031-C dated 14-09-2018 Rs.20,000/- Dated 14-09-2018

	Composition	Each 100gm Contains: Amoxicillin as Trihydrate…25gm Colistin Sulphate…100mg
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	100gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 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 December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	Me too not verified, COLI-A Powder (044941) EACH 100GM CONTAINS:- AMOXICILLIN SODIUM ..23GM. COLISTIN SULPHATE… 100MIU.
	Decision of 287: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Remarks:** Firm revised the formulation along with Form 5 with 5000/-fee (Challan # 0807340) Each 100gm Contains: Amoxicillin Trihydrate…23 gm Colistin Sulphate…100 MIU **Me-too status :** Pentamox Water Soluble Powder (071018)	
	Decision:Approved with innovator's specification.	
978.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-Colamox Powder
	Diary No. Date of R& I & fee	Form-5 Dy.No 31031-O dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Composition	Each 100gm Contains: Spectinomycin as HCL…5gm Colistin Sulphate…50 MIU Amoxicillin Trihydrate…10gm Bromhexine HCL…0.5gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	100gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 kg, 10 kg, 25 kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	COLIBAC-SP 160 POWDER of Nawan pharma
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	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. **Remarks:** **Me too,** AS-PLUS WATER SOLUBLE POWDER (071063) is confirmed	
	Decision:Approved with innovator's specification.	
979.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Stepcin-C Powder
	Diary No. Date of R& I & fee	Form-5 Dy.No 26772-G dated 03-08-2018 Rs.20,000/-

		Dated 03-08-2018
	Composition	Each KG Contains: Colistin sulphate …60 MIU Procaine Penicillin…12 gm Streptomycin sulphate…..36 gm Zinc bacitracin……52 gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	100gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 kg, 10 kg, 25 kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	PROCAIN SB WATER SOLUBLE POWDER (Not confirmed)
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	
	Decision of 287: Deferred for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were adopted by the Registration Board in its 275th meeting. **Remarks:** Me too is confirmed now, Procain Sb Plus Water Soluble Powder (058954)	
	Decision:Approved with innovator's specification.	
980.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Stepcin Powder
	Diary No. Date of R& I & fee	Form-5 Dy.No 26772-G dated 03-08-2018 Rs.20,000/- (Duplicate) Dated 03-08-2018
	Composition	Each Kg Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…(10%)25gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	5 gm, 10 gm, 25 gm, 50 gm, 100 gm, 200 gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 kg, 10 kg, 15 kg, 2 kg and 25 kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Procain Sb Water Soluble Powder (058955)
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	
	Decision of 287: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Remarks:** Firm revised the formulation along with Form 5 with 5000/-fee (Challan # 0807342) Each Kg Contains: Procaine Penicillin…12gm Streptomycin Sulphate…36gm Zinc Bacitracin…50 gm **Me-too status :** Procain Sb Water Soluble Powder (058955)	
	Decision:Approved with innovator's specification.	
981.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore

	Brand Name +Dosage Form + Strength	I-Amoxycol DS Powder (Vet)
	Diary No. Date of R& I & fee	Form-5 Dy.No 31031-L dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Composition	Each 100gm Contains: Amoxicillin Trihydrate…200mg Colistin Sulphate…600,000 MIU
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	5 gm, 10 gm, 25 gm, 50 gm, 100 gm, 200 gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 kg, 10 kg, 15 kg, 2 kg and 25 kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	NA
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	Me too evidence not present
	Decision of 287: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. **Remarks:** Firm revised the formulation along with Form 5 with 5000/-fee (Challan # 0807339) Each Gm Contains: - Amoxycillin Trihydrate 200mg. Colistin Sulphate 800,000 Units. **Me-Too Status Amoxycol Water Soluble Powder.** (035110)	
	Decision:Approved with innovator's specification.	

Case no. 04 Registration Applications of Import Cases.

a. Deferred cases

i. Human

982.	**Name and address of Applicant**	M/S Huaxing pharmaceuticals Pvt. Ltd. Address: 207,D1, Nespak society district Lahore. By M/S Shandong Luoxin pharmaceutical group stock limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Detail of Drug Sale License	**Address**: Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore **Validity:** 28-june 2018 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/S Shandong Luoxin pharmaceutical group stock co. limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Name and address of marketing authorization holder	Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore
	Name of exporting country	People's republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.23500 Dated 6-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 6-july-2018
	Brand Name +Dosage Form + Strength	Aciclovir tablet 0.1 g tablet
	Composition	Each tablet contain Acyclovir…. 100 mg

	Finished Product Specification	USP
	Pharmacological Group	Anti-viral
	Shelf life	24 month
	Demanded Price	200 rupees per box
	Pack size	
	International availability	NA
	Me-too status	NA
	Detail of certificates attached	**GMP certificate** **(Translated Copy, attested)** **Certificate No**:SD20160446 **Certifying Authority:** China food and drug administration **Issue date:** 25-1-2016 **Valid date:** 24-1-2021 **COPP (Original, Embassy Attested)** **Certificate No**:LY2018-013 **Certifying Authority:** Shandong Linyi food and drug administration **Issue Date:**1-01-2016 Valid: 18-3-2019 **Letter of Authorization (Copy)** Date of Agreement:12-march-2018 (Valid for 5 year)
	Remarks of the Evaluator.	• Label specimen was without the Urdu version which is required as per The Drugs (Labelling and Packaging) Rules, 1986 was Submitted • Not found in any reference regulatory authority in this strength • Evidence of approval of applied formulation in DRAP (me too status) Not approved in this strength • Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) Stability data for 3 batches is submitted . however on query new stability specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm commit to complete the stability study of 3 commercial batches up to shelf life. • Detailed method of manufacturing of tablet was missing on query it was Submitted
	Decision of 286: Deferred for submission of stability study data as per zone IV A. **Remarks:** Stability data is not submitted. Previously due to the location of the manufacturer and the applicant, initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH). However on query firm provides the undertaking to provide stability study of 3 commercial batches on Zone IV-A conditions.	
	Decision: Deferred for submission of stability studies both accelerated & real time for three batches of applied drug product conducted in accordance with zone IV-A conditions.	
983.	Name and address of Applicant	M/S Huaxing pharmaceuticals Pvt. Ltd. Address: 207,D1, Nespak society district Lahore. By M/S Shandong Luoxin pharmaceutical group stock limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Detail of Drug Sale License	**Address**: Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207, D1, Nespak society district Lahore

		Validity: 28-june 2018 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/S Shandong Luoxin pharmaceutical group stock co. limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Name and address of marketing authorization holder	Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore
	Name of exporting country	People's republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.23497 Dated 6-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 6-july-2018
	Brand Name +Dosage Form + Strength	Aniracetam capsule 0.2 g
	Composition	Each Capsule contain aniracetam…. 0.2 g
	Finished Product Specification	In-house
	Pharmacological Group	Antidepressant, Mental performance enhancer
	Shelf life	24 month
	Demanded Price	600 rupees per bottle
	Pack size	18 capsules per bottle
	International availability	NA
	Me-too status	NA
	Detail of certificates attached	**GMP certificate** **(Translated Copy, attested)** **Certificate No**:SD20160446 **Certifying Authority:** China food and drug administration **Issue date:** 10- July 2002 **Valid date:** 24-1-2021 **COPP (Original, Embassy Attested)** **Certificate No**:LY2018-018 **Certifying Authority:** Shandong Linyi food and drug administration **Issue Date:**9-12-2005 Valid: 18-3-2019/ **Letter of Authorization (Copy)** Date of Agreement:12-march-2018 (Valid for 5 year)
	Remarks of the Evaluator.	• Submitted Label specimen is without the Urdu version which is required as per The Drugs (Labelling and Packaging) Rules, 1986 Submitted • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. Not approved in any reference regulatory authority • Evidence of approval of applied formulation in DRAP (me too status). Not approved in DRAP • Stability data is not submitted. Submit stability studies (long term & accelerated) conducted under the conditions of zone IV-A of 03 batches duly signed shall be submitted. Not Provided Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) Stability data for 3 batches is submitted . however on query new stability

		specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm commit to complete the stability study of 3 commercial batches up to shelf life. • Detailed method of manufacturing of tablet is missing Submitted • Complete protocols of stability studies are needed. Submitted
	Decision of 286: Deferred for submission of stability study data as per zone IV A. **Remarks:** Stability data is not submitted. Previously due to the location of the manufacturer and the applicant, initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH). However on query firm provides the undertaking to provide stability study of 3 commercial batches on Zone IV-A conditions.	
	Decision:Deferred for submission of stability studies both accelerated & real time for three batches of applied drug product conducted in accordance with zone IV-A conditions.	
984.	Name and address of Applicant	M/S Huaxing pharmaceuticals Pvt. Ltd. Address: 207,D1, Nespak society district Lahore. By M/S Shandong Luoxin pharmaceutical group stock limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Detail of Drug Sale License	**Address**: Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore **Validity:** 28-june 2018 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/S Shandong Luoxin pharmaceutical group stock co. limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Name and address of marketing authorization holder	Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore
	Name of exporting country	People's republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.23496 Dated 6-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 6-july-2018
	Brand Name +Dosage Form + Strength	Calcium Folinate injection
	Composition	Each vial contain Calcium folinate….100 mg
	Finished Product Specification	USP
	Pharmacological Group	Detoxifying agent for antineoplastic treatment
	Shelf life	24 months
	Demanded Price	1800 per vial
	Pack size	1's vial
	International availability	Leucovorin Calcium 100 mg/vial (USFDA)
	Me-too status	leucovorin calcium (Atco)
	Detail of certificates attached	**GMP certificate** **(Translated Copy, attested)** **Certificate No**:SD20160446 **Certifying Authority:** China food and drug administration **Issue date:** 10- July 2002 **Valid date:** 24-1-2021 **COPP (Orignal, Embassy Attested)** **Certificate No**:LY2018-019

		Certifying Authority: Shandong Linyi food and drug administration **Issue Date:**31-March-2005 Valid: 18-3-2019 **Letter of Authorization (Copy)** Date of Agreement:12-march-2018 (Valid for 5 year)
	Remarks of the Evaluator.	• **Submitted Label specimen is without the Urdu version which is required as per The Drugs (Labelling and Packaging) Rules, 1986** Submitted • **Stability data is not submitted. Submit stability studies (long term & accelerated) conducted under the conditions of zone IV-A of 03 batches duly signed shall be submitted.** Not Provided Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) Stability data for 3 batches is submitted . however on query new stability specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm commit to complete the stability study of 3 commercial batches up to shelf life. • **Complete protocols of stability studies are needed**. Submitted
	Decision of 286: Deferred for submission of stability study data as per zone IV A. **Remarks:** Stability data is not submitted. Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH) However on query firm provides the undertaking to provide stability study of 3 commercial batches on Zone IV-A conditions.	
	Decision:Deferred for submission of stability studies both accelerated & real time for three batches of applied drug product conducted in accordance with zone IV-A conditions.	
985.	Name and address of Applicant	M/S Huaxing pharmaceuticals Pvt. Ltd. Address: 207,D1, Nespak society district Lahore. **By:** M/S Shandong Luoxin pharmaceutical group stock limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Detail of Drug Sale License	**Address**: Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore **Validity:** 28-june 2018 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/S Shandong Luoxin pharmaceutical group stock co. limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Name and address of marketing authorization holder	Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore
	Name of exporting country	People's republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.23499 Dated 5-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 6-july-2018
	Brand Name +Dosage Form + Strength	Cefprozil tablet 0.25g
	Composition	Each Film coated tablet contain Cefprozil…..0.2g
	Finished Product Specification	USP
	Pharmacological Group	Cephalosporin

	Shelf life	24 months
	Demanded Price	720 rupees per box
	Pack size	8 tablets/box
	International availability	CEFPROZIL (CEFPROZIL) tablet LUPIN
	Me-too status	NA
	Detail of certificates attached	**GMP certificate** **(Translated Copy, attested)** **Certificate No**:SD20160446 **Certifying Authority:** China food and drug administration **Issue date:** 10- July 2002 **Valid date:** 24-1-2021 **COPP (Copy, Embassy Attested)** **Certificate No**:LY2018-008 **Certifying Authority:** Shandong Linyi food and drug administration **Issue Date:**27-March-2005 Valid: 18-3-2019 **Free Sale certificate: (Original)** **Certificate No**:LYFSC2018-003 **Certifying Authority:** Shandong food and drug administration of the people's republic of china **Issue Date:**19-March-2018 **Letter of Authorization (Copy)** Date of Agreement:12-march-2018 (Valid for 5 year)
	Remarks of the Evaluator.	• Submitted Label specimen is without the Urdu version which is required as per The Drugs (Labelling and Packaging) Rules, 1986 Submitted • Evidence of approval of applied formulation in DRAP (me too status) not available. Evidence of cefprozil capsule is provided not of tablet • Stability data is not submitted. Submit stability studies (long term & accelerated) conducted under the conditions of zone IV-A of 03 batches duly signed shall be submitted. Not Provided Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) Stability data for 3 batches is submitted . however on query new stability specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm commit to complete the stability study of 3 commercial batches up to shelf life. • **Complete protocols of stability studies are needed.** Submitted
	Decision of 286: Deferred for consideration on its turn with respect to the queue. **Remarks:** Stability data is not submitted. Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH) However on query firm provides the undertaking to provide stability study of 3 commercial batches on Zone IV-A conditions.	
	Decision:Deferred for submission of stability studies both accelerated & real time for three batches of applied drug product conducted in accordance with zone IV-A conditions.	

986.	Name and address of Applicant	M/S Huaxing pharmaceuticals Pvt. Ltd. Address: 207,D1, Nespak society district Lahore. By M/S Shandong Luoxin pharmaceutical group stock limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Detail of Drug Sale License	**Address**: Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore **Validity:** 28-june 2018 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/S Shandong Luoxin pharmaceutical group stock co. limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Name and address of marketing authorization holder	Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore
	Name of exporting country	People's republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.23487 Dated 6-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 6-july-2018
	Brand Name +Dosage Form + Strength	Oxaliplatin injection
	Composition	Each Vial Contains: Oxaliplatin….. 100mg lyophilized powder for IV injections
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic Drug
	Shelf life	24 months
	Demanded Price	10,000 rupies per vial
	Pack size	8 tablets/box
	International availability	ELOXATIN for injection (50mg 100mg) by M/s SANOFI AVENTIS US, USFDA approved
	Me-too status	Me-too status Celdach 50 injection by Hakimsons (Reg # 72564)
	Detail of certificates attached	**GMP certificate** **(Translated Copy, attested)** **Certificate No**:SD20160446 **Certifying Authority:** China food and drug administration **Issue date:** 10- July 2002 **Valid date:** 24-1-2021 **COPP (Original, Embassy Attested)** **Certificate No**:LY2018-017 **Certifying Authority:** Shandong Linyi food and drug administration **Issue Date:** 11-Dec-2012 Valid: 18-3-2019 **Free Sale certificate:** **Certificate No**:LYFSC2018-012 **Certifying Authority:** Shandong food and drug administration of the people's republic of china **Issue Date:**19-March-2018 **Letter of Authorization (Copy)** Date of Agreement:12-march-2018 (Valid for 5 year)

	Remarks of the Evaluator.	• Submitted Label specimen is without the Urdu version which is required as per The Drugs (Labelling and Packaging) Rules, 1986 Submitted • Stability data is not submitted. Submit stability studies (long term & accelerated) conducted under the conditions of zone IV-A of 03 batches duly signed shall be submitted. <u>Not Provided</u> Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) Stability data for 3 batches is submitted . however on query new stability specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm commit to complete the stability study of 3 commercial batches up to shelf life. • Finished product specifications (along with the official monograph if the product is pharmacopoeial). The firm has claimed In House manufacturing specifications while the product is available in USP. As per USP the product contains Oxaliplatin and Lactose monohydrate while according to formulation provided by the firm the product also contain Oxaliplatin and lactose. • Complete protocols of stability studies are needed. Submitted
	Decision of 286: Deferred for submission of stability study data as per zone IV A. **Remarks:** Stability data is not submitted. Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH) However on query firm provides the undertaking to provide stability study of 3 commercial batches on Zone IV-A conditions.	
	Decision:Deferred for submission of stability studies both accelerated & real time for three batches of applied drug product conducted in accordance with zone IV-A conditions.	
987.	Name and address of Applicant	M/S Huaxing pharmaceuticals Pvt. Ltd. Address: 207,D1, Nespak society district Lahore. By M/S Shandong Luoxin pharmaceutical group stock limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Detail of Drug Sale License	**Address**: Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore **Validity:** 28-june 2018 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/S Shandong Luoxin pharmaceutical group stock co. limited Road Luo 7, High & New technology industries development zone, Linyi city, Shandong province china.
	Name and address of marketing authorization holder	Huaxing Pharmaceuticals (Pvt) Ltd. Address: 207,D1, Nespak society district Lahore
	Name of exporting country	People's republic of China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.23487 Dated 6-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 6-july-2018
	Brand Name +Dosage Form + Strength	Ambroxol HCL tablets

	Composition	Each tablet contain ambroxol hydrochloride…. 30 mg
	Finished Product Specification	in-house
	Pharmacological Group	Respiratory system
	Shelf life	24 months
	Demanded Price	240 rupees per box
	Pack size	8 tablets/box
	International availability	AMBROXOL ARROW 30 mg tablet (ANSM)
	Me-too status	FLUIBRON of CHIESI PHARMACEUTICALS
	Detail of certificates attached	**GMP certificate** **(Translated Copy, attested)** **Certificate No**:SD20160446 **Certifying Authority:** China food and drug administration **Issue date:** 10- July 2002 **Valid date:** 24-1-2021 **COPP (Original, Embassy Attested)** **Certificate No**:LY2018-006 **Certifying Authority:** Shandong Linyi food and drug administration **Issue Date:** 11-Dec-2012 Valid: 2020-2-7 **Free Sale certificate:** **Certificate No**:LYFSC2018-20 **Certifying Authority:** Shandong food and drug administration of the people's republic of china **Issue Date:**19-March-2018 **Letter of Authorization (Copy)** Date of Agreement:12-march-2018 (Valid for 5 year)
	Remarks of the Evaluator.	• Submitted Label specimen is without the Urdu version which is required as per The Drugs (Labelling and Packaging) Rules, 1986 Label with Urdu version is submitted • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Approved in France • Stability data is not submitted. Submit stability studies (long term & accelerated) conducted under the conditions of zone IV-A of 03 batches duly signed shall be submitted. Not Provided Previously due to the location of the manufacturer and the applicant initial stability study was carried out under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) Stability data for 3 batches is submitted . however on query new stability specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm commit to complete the stability study of 3 commercial batches up to shelf life. • Complete protocols of stability studies are needed. Submitted
	Decision of 286: Deferred for consideration on its turn with respect to the queue. **Remarks:** Stability data is submitted. Previously due to the location of the manufacturer and the applicant, initial stability study was carried out	

	under the condition of zone-II (25°C ± 2°C / 60% ± 5% RH). However on query regarding stability specific to zone IV A (30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH) firm provides the stability study of 3 commercial batches for 6 months.	
	Decision:Deferred for submission of stability studies both accelerated & real time for three batches of applied drug product conducted in accordance with zone IV-A conditions.	

ii. Veterinary

988.	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**: M/s Vet line international Flat # 55/5, first floor, main shadman market, Lahore. **Renewal:** 11-2-2019 **Status:** Drug License by Way of distributor
	Name and address of manufacturer	M/s Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia
	Name and address of marketing authorization holder	M/s Range Pharma Sdn. Bhd. No.1, Jalan TSB 11, Taman Industri Sungai Buloh, 47000 Sungai Buloh, Selangor Darul Ehsan, Malaysia
	Name of exporting country	Malaysia
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.26357 Dated 28-12-2017
	Fee including differential fee	Rs. 100,000/- Dated 28-12-2017
	Brand Name +Dosage Form + Strength	Neocin 49% Powder
	Composition	Each g Contains: Neomycin as Sulphate…490 mg
	Finished Product Specification	Manufacturer
	Pharmacological Group	Anti-infective
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100 g, 500 g, 1000g, 25 kg
	International availability	NA (present in 500 mg strength)
	Me-too status	NA
	Detail of certificates attached	Free Sale certificate (Original , Notary Attested, Embassy attested) Certificate No:CFS-025H/2017 Certifying Authority: NPRA ministry of health Malaysia Issue Date: 31-May-2017 Certificate of pharmaceutical products (COPP): Certificate No: 0476H/2017 Certifying Authority: Malysia Drug control authority Date of issue: 27-July 2017 GMP certificate (Copy, Notary Attested, Embassy attested) Certificate No:061/17 Certifying Authority: NPRA ministry of health Malaysia Issue Date: 13-November 2015 Agency agreement: (Notary Attested, Embassy attested)
	Remarks of the Evaluator.	Evidence of me too not provided, Provided reference (DUFAMOX 50% WATER SOLUBLE POWDER)contain 500 mg/g not 490mg.
	Decision of 287: 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. **Remarks of the Evaluator:**	

	The firm provide the international reference of "AQUAMICIN polvo" approved in Spain (https://cimavet.aemps.es/cimavet/pdfs/es/p/1242+ESP/P_1242+ESP.pdf) but the provided reference has Each g contains: Neomycin sulfate .....490.000 IU Not 490 mg. The firm claim that 1000 IU =1 mg neomycin Hence 490,000IU/g=490mg/g (Ref: Chines pharmacopeia)
	Decision: Approved with innovator's specification.

Case No. 05 Registration Applications of Drugs for which Stability Study Data is Submitted

a. Verification of stability study data

11	**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**
989.	M/s Getz Pharma (Pvt) Ltd., 29-30/27, Korangi Industrial Area, Karachi.	Estine tablets 20 mg Each orodespersable tablet contains: Ebastin….20 mg (Anti histamine)	Form-5-D Dy. No: 11909 Dated.6-6-2017 Rs.50,000/- (29-10-2015) 10's ; Rs. 316/-	EBASTINE TEVA 20 mg, France ANSM GMP inspection report conducted on Last inspection was conducted on --------- with no observation

STABILITY STUDY DATA			
Drug	Estine tablets 20 mg		
Name of Manufacturer	M/s Getz Pharma (Pvt) Ltd., 29-30/27, Korangi Industrial Area, Karachi.		
Manufacturer of API	**Ebastine:** Bal Pharmaceuticals, unit II, 61-B Bommasandra industrial area Bangalore		
API Lot No.	**Ebastine:** 500111706023		
Description of Pack (Container closure system)	Alu Alu blister		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH 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.	418DS01	418DS02	418DS03
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	1-2018	1-2018	2-2018
Date of Initiation	21-3-2018	21-3-2018	21-3-2018
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.	**Ebastine:** Copy of GMP certificate issued Bal Pharmaceuticals limited, unit II, 61-B Bommasandra industrial area Bangalore. Karnataka India. Dated 5 April 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.	**Ebastine:** Copy of commercial invoice has been submitted issued by ADC, Karachi DRAP.
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
i.	On COA unit II is mentioned clarification is required wethere GMP provided is of same plant or not?	The Firm claimed that the GMP certificate provided is of the same unit as mentioned on COS of AP. Declaration by Bal Pharma India states that the complete address of unit II I,e, 61-B Bommasandra industrial area Bangalore 560 099, India is in line with address mentioned in GMP certificate.
i.	Stability data of API from manufacturer is needed	Provided
i.	Clarification is required regarding the time gap of almost 2 months between manufacturing and stability study as manufacturing date is 21-1-2018 and stability study starting date is 21-3-2108	This is to inform that every new entry 3 batches are manufactured. Therefore for the maximum utility of equipment, chemical reagents and analyst lean process approach is being used in Getz pharma where we performed initial testing of all 3 batches of same product simultaneously. Since the 3rd batch of estine 20 mg was manufacture on 8-3-2018 therefore we complete the analysis of all the 3 batches on 20-3-2018 and charge them on stability on 21-3-2018

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Estine (Ebastine) 10mg & 20mg Oro-dispersible Tablets by M/s Getz Pharma Pvt. Limited, 29-30/27, Korangi Industrial Area , Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 25th April, 2019.
Investigation Date and Time: 6th May, 2019. (Forenoon)
Investigation Site: Factory premises of M/s Getz Pharma Pvt. Limited, 29-30/27, Korangi Industrial Area, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Getz Pharma Pvt. Limited, 29-30/27, Korangi Industrial Area, Karachi for registration of Estine (Ebastine) 10mg & 20mg Oro-dispersible 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, Dean Faculty of Pharmacy, Ziauddin University. (Member Registration Board)
2. Dr. Kirshan Das, Assistant Director, 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:
Estine (Ebastine) Tablets 10mg & 20mg, Oro-dispersible Tablets

Q.#	Question	Observation by panel
1	Do you have documents confirming the import of Ebastine API including approval from DRAP?	The firm has imported "Ebastine API" from M/s Bal Pharma Ltd, India and has approval from DRAP for import vide License No.1657/17-DRAP (K) dated 21.06.2017.
2	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through Postal Audit checklist / Physical Site Inspection and availability of valid GMP approval by competent authority. Further, M/s Bal Pharma Ltd, India has Certificate of Suitability (CEP) for Ebastine API issued by European Directorate for the Quality of Medicines & HealthCare (EDQM).
3	Do you have documents confirming the import of Ebastine reference standard and impurity standards?	Firm has imported Ebastine working standard from M/s Bal Pharma Ltd, India vide invoice No. SAM-010 dated 14.06.2017. For impurity testing, firm has used Relative Retention Time (RRT) for location and calculation of impurities as provided by Ph. Eur.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificate of analysis for API and working standard.
5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has provided copy of valid GMP certificate of M/s Bal Pharma Ltd, India valid till 04-02-2020.
6	Do you use API manufacturer method of testing for testing API?	The firm has used method of testing adopted from European Pharmacopeia (Ph. Eur) monograph for Ebastine API and the same has been verified as per USP chapter 1226 (verification of compendial procedure)
7	Do you have stability studies reports on API?	The firm has 5 years real time stability study data provided by API manufacturer.
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?	Yes, the firm has method for quantifying the impurities in the API adopted from European Pharmacopeia (Ph. Eur)

<table>
<tr><td></td><td></td><td>monograph for Ebastine 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 some remaining quantities of the API and working standard.</td></tr>
<tr><td>11</td><td>Have you used pharmaceutical grade excipients?</td><td>The firm have used pharmaceutical grade excipients which include Microcrystalline Cellulose (Avicel PH-101), Mannitol, Poloxamer 188, Povidone K-30, Hypromellose, Carboxymethylcellulose Calcium, Colloidal Anhydrous Silica, Croscarmellose Sodium, Crospovidone, Aspartame, Trusil Powder Orange Flavour and Magnesium Stearate.</td></tr>
<tr><td>12</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm has necessary 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>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 Ebastine tablets?</td><td>The firm has written and authorized protocols for the development of Ebastine Oro-dispersible Tablets 10mg & 20mg.</td></tr>
<tr><td>15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>The firm has performed Drug-excipient compatibility studies and concluded that the excipients used in the proposed formulation of Ebastine Oro-dispersible Tablets 10mg & 20mg are compatible with the API.</td></tr>
<tr><td>16</td><td>Have you performed comparative dissolution studies?</td><td>The firm has used dissolution criteria as per Japanese Pharmacopoeia monograph for Ebastine Oro-dispersible Tablets and the product complies. Further, this product is orally dispersible which disintegrates very rapidly. The release is more than 85% within 15 minutes, therefore, F2 waiver is applicable.</td></tr>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm has dedicated product development (R&D) section with requisite manufacturing and analysis facilities.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of Ebastine tablets?</td><td>The firm has necessary equipment available in product development section for development ofEbastine Oro-dispersible Tablets 10mg & 20mg.</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 proper maintenance / calibration with re-qualification program for the equipment used in 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 in product development section with proper knowledge and training in product development. There are 50 Scientists (Pharmacist & Chemist) working only in R&D Section.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of Ebastine tablets as required?</td><td>The firm has manufactured three stability batches of Ebastine Oro-dispersible Tablets 10mg & 20mg. Packed in Alu-Alu blisters:
<table>
<tr><td colspan="3">Ebastine Tablets 10mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>418DS01</td><td>January 2018</td><td>2500 Tablets</td></tr>
<tr><td>418DS02</td><td>January 2018</td><td>2500 Tablets</td></tr>
<tr><td>418DS03</td><td>February 2018</td><td>2500 Tablets</td></tr>
</table>
<table>
<tr><td colspan="3">Ebastine Tablets 20mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>419DS01</td><td>January 2018</td><td>4000 Tablets</td></tr>
<tr><td>419DS03</td><td>February 2018</td><td>4000 Tablets</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td><table><tr><td>419DS04</td><td>March 2018</td><td>4000 Tablets</td></tr></table></td></tr>
<tr><td>23</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the capacity of their R&D equipment where probable simulation of manufacturing procedure of production batches are expected as well as quantity of tablets 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 complete record of production of stability batches. All the Log Books are properly maintained.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocols for stability testing of stability batches having protocol number:<table><tr><td colspan="2">Ebastine Tablets 10mg</td></tr><tr><td>Batch No.</td><td>Protocol No.</td></tr><tr><td>418DS01</td><td>FS-019-18</td></tr><tr><td>418DS02</td><td>FS-020-18</td></tr><tr><td>418DS03</td><td>FS-021-18</td></tr></table><table><tr><td colspan="2">Ebastine Tablets 20mg</td></tr><tr><td>Batch No.</td><td>Protocol No.</td></tr><tr><td>419DS01</td><td>FS-022-18</td></tr><tr><td>419DS03</td><td>FS-023-18</td></tr><tr><td>419DS04</td><td>FS-024-18</td></tr></table></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 the method for testing of stability batches.</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 given by any other lab?</td><td>The firm has developed and validated method of testing for finished product and complete Method Validation Report is available. Therefore, method transfer is not applicable.</td></tr>
<tr><td>28</td><td>Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Ebastine API and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Ebastine API and the finished drug.</td></tr>
<tr><td>29</td><td>Do your method of analysis stability indicating?</td><td>The firm has performed forced degradation (FD) study on their product Ebastine Oro-dispersible Tablets 10mg & 20mg for the conformance of its stability indicating nature.</td></tr>
<tr><td>30</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software is 21CFR Compliant as per record available with the firm. The firm have WATER's HPLC with Empower 3 software having following features:
Have Audit trail
Have backup system
Have Data traceability
Have Data achieving system
Have data integrity
Have Data security
System Security Policy</td></tr>
<tr><td>31</td><td>Can you show Audit trail reports on Ebastine testing?</td><td>Audit trail on the testing reports is available.</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 stability batches kept on stability testing?</td><td>The firm has three stability batches kept on real time stability testing. 12 months real time stability data is available.</td></tr>
<tr><td>34</td><td>Do you have valid calibration status for the equipments used in Ebastine tablets production and analysis?</td><td>The firm has valid calibration status for the equipment used in production and analysis of Ebastine Oro-dispersible Tablets 10mg & 20mg.</td></tr>
<tr><td>35</td><td>Do proper and continuous monitoring and</td><td>Adequate monitoring and control are available for</td></tr>
</table>

	control are available for stability chamber?	stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Estine (Ebastine) 10mg & 20mg Oro-dispersible 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 Estine 10mg & 20mg Oro-dispersible Tablets.

Recommendations:

The firm may kindly be granted necessary registration of Estine 10mg & 20mg Oro-dispersible tablets

Decision: Registration Board decided to approve registration of "Ebastine tablets 20 mg by M/s Getz Pharma (Pvt) Ltd., Karachi, with the change in brand name. 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 GMP Inspection Report Date & Remarks
990.	M/s Sante Pvt Ltd 245/2-Z, Block 6, PECHS, Karachi 75400	Zithrosan 1% eye drops Each 10 ml contains: Azithromycin as dihydrate ……10 mg (Anti-biotic) In-house Specifications	Form-5-D Dy. No: 09 Dated: 31-1-2013 Rs.20,000/- + 30,000 (Callan: 0033070, dated= 20/1/2014) Duplicated 2.5 ml (Deferred in 245 meeting for application on Form-5 D and balance fee)	Azasite by Oak pharma (USFDA) Last inspection was conducted on 20-8-2018 for renewal / grant of GMP Certificate and the report concludes good compliance of GMP.

STABILITY STUDY DATA

Drug	Zithrosan 1% eye drops
Name of Manufacturer	M/s Sante Pvt Ltd 245/2-Z, Block 6, PECHS, Karachi 75400
Manufacturer of API	**Azithromycin:** Ningxia Qiyuan pharmaceuticals co. Ltd. No. 1 Street, wangyuan industrial area, Yinchuan Ningxia China
API Lot No.	161015-1111
Description of Pack (Container closure system)	2.5 ml filled in 5ml PP bottle, LDP nozzle and HDPE cap
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH
Time Period	Real time: 6 months Accelerated: 12 months
Frequency	Accelerated: 0,3,6 (month) Real Time: 0,3,6 (month)

Batch No.	06T	07T	08T
Batch Size	1 liter	1 liter	1 liter
Manufacturing Date	3-2017	3-2017	3-2017
Date of Initiation	3-2017	3-2017	3-2017
No. of Batches	03		
Storage condition	2-8 ºC		
Date of Submission	28-9-2018 (Dy. No. 32409)		

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 to M/s Ningxia Qiyuan pharmaceuticals co. Ltd. No. 1 Street, wangyuan industrial area, Yinchuan Ningxia China Issued by Ningxia food and drug administration
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.	**Azithromycin:**Copy of commercial invoice has been submitted, manufacturer is M/s Ningxia Qiyuan pharmaceuticals co. Ltd. No. 1 Street, wangyuan industrial area, Yinchuan Ningxia China Issued by ADC Karachi DRAP quantity issued of azithromycin is 75 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 provided 06 Months Accelerated and 6 Months Real Time Stability Data for 03 Batches.

Sr.#	Deficiency/Observation	Response by Pharma.
i.	On submitted GMP certificate of supplier of API (azithromycin), issuing Drug regulatory authority is not clear.	Issuing authority is Ningxia food and drug administration
ii.	Clarification is required, regarding variation in run time of chromatograms in assay and dissolution analysis.	Firm responded that, Due to change of HPLC system (as we have 4 HPLC). Run time also depend upon source of organic solvents in mobile solvents in mobile phase. We use ACN/MeOH of merck and sigma. Sometime run time shifts due to weak signal strength of D2 lamp and also efficiently of column may effect run time. Also USP states in most of its methods, "Make adjustments if necessary". Secondly if to reduced tailing factors and peak adjustment, we change mobile

		phase 4 to 5% (USP allowed 20%) the retention time shift. Moreover the run time within the span of analysis is not varying and the runtime of standard and sample during analyses is same as per requirement.
iii.	Detailed method of testing including assay, pH and sterility etc. is not provided along with the stability protocols and specifications	Submitted
iv.	Clarification is required, since the pack size and packaging material of container	Submitted

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Zithrosan 1% Eye Drops (Azithromycin as dehydrate) by M/s. Sante (Pvt). Ltd., 245/2-Z, Block-6, PECHS, Karachi.

Reference No: F.13-11/2017-PEC(Pt) dated 18th January, 2019.
Investigation Date and Time: 14th March, 2019 (Morning).
Investigation Site: Factory premises of M/s. Sante (Pvt). Ltd., Karachi.

Background:

Chairman Registration Board considered the applications of M/s Sante (Pvt). Ltd., Karachi for registration of Zithrosan 1% Eye Drops (Azithromycin as dehydrate) 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. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
2. Dr. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board, Islamabad.
3. Dr. Sidra Yasmeen, Assistant Director, DRAP Office, 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:

Sr. No.	Question	Observation by panel
1	Do you have documents confirming the import of API?	The firm has used 34.26g quantities for manufacturing of three stability batches (1 litre each) of Zithrosan 1% eye drops, from 75 kg API (Azithromycin Dihydrate - tablet grade) imported for production of their registered product, Azithromycin tablets vide invoice No. 201610103 dated 25th October, 2016 from M/S. Ningxia Qiyuan Pharmaceutical Co. Ltd., China. The firm has got proper approval from DRAP,

Sr. No.	Question	Observation by panel
		Office, Karachi.
2	What was the rationale behind selecting the particular manufacturer of API?	No ophthalmic grade API has been imported by the firm for manufacturing of stability batches of Zithrosan 1% eye drops, however, the API primarily imported for tablet manufacturing has been selected as per approved vendor certification program.
3	Do you have documents confirming the import of the API, reference standard of the API and impurity standards of the API?	The firm has documents confirming the import of API and working standard of the API. No impurity standard has been imported by the firm irrespective of the fact that the API has a number of known specified impurities like Azithromycin-N-oxide, N-dimethyl Azithromycin, Azithromycin A, P etc.
4	Do you have certificate of Analysis of the API, reference standards and impurity standard?	The firm has certificates of analysis for the API and working standard of the API.
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 API manufacturer issued by the concerned regulatory authority of country of origin (China).
6	Do you use API manufacturer method of testing?	The firm has used In-house method for testing of the API.
7	Do you have stability studies reports on API?	The firm has stability studies reports on API conducted by the API manufacturer.
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 product 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 some remaining quantities of the API and working standard of the API only.
11	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients. The excipients include: Mannitol, Citric Acid (Anhydrous), Sodium Citrate (Dihydrate), Poloxamer 407, Benzalkonium Chloride, CMC, Sodium Chloride, EDTA &Sodium Hydroxide Pellets.
12	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the import of some excipients; however, major excipients have been purchased locally.
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 Zithrosan 1% Eye Drops?	The firm has written and authorized protocols for the development of Zithrosan 1% Eye Drops (Azithromycin). However, the protocol has not been used completely.
15	Have you performed Drug-excipient compatibility studies?	The firm has not performed Drug-excipients compatibility studies irrespective of the fact that the formulation of Zithrosan 1% Eye Drops is different from the innovator product (Azasite 1% Solution, by M/s. Inspire Pharmacueticals, USA).
16	Have you performed comparative studies?	The firm has not performed comparative studies with the innovator product. The innovator product is even not procured by the firm.
17	Do you have product development (R&D) section?	The firm has an R&D Lab provided with some equipment.
18	Do you have necessary equipment available in product development section for development	As Above.

Sr. No.	Question	Observation by panel
	of Eye Drops?	
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 02 qualified staff (pharmacists) in manufacturing part whereas 04 personnel (03 chemists and 01 pharmacists) in analytical part of the product development.
22	Have you manufactured three stability batches for the stability studies of Zithrosan 1% Eye Drops as required?	The firm has manufactured three stability batches for accelerated and real time stability studies of Zithrosan 1% Eye Drops with batch No. 06T, 07T & 08T each of 1Litre quantity. Tablet grade material has been used with 5% overage for manufacturing of eye drops. Literature survey of Azasite 1% ophthalmic solution (innovator product) clearly indicate that the eye drops are in solution form without any overage whereas the firm's product is in suspension form with 5% overage. Moreover, the development protocol of the firm shows that filteration be used for sterilization of the final product however, the filteration process for ophthalmic suspension is inappropriate process. The firm actually has not sterilized the suspension besides the fact that they have conducted the sterility testing in the stability testing program.
23	What were the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of test and their frequencies.
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 have been available with the firm.
25	Do you have protocols for stability testing of stability batches?	The firm has 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 the method for testing stability batches. However, the method is an isocratic method being validated without the use of impurity standards and forced degradation studies hence the method is non-stability indicating and not validated properly as per guidelines.
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 at this stage.
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 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 method of analysis is not stability indicating. The accelerated stability studies report (Batch # 08T) show the assay results as under: 100.14% (0 month), 107.78% (3 months) and 114.55% (6 months). Hence there is significant change within three months time. The real time stability reports on all three trial batches (06T, 07T and 08T) show that the assay results have crossed the

Sr. No.	Question	Observation by panel
		specifications (90.0 % to 110.0%) at 12 months i.e. Batch # 06T (118.81%), 07T (118.94%) and 08T (119.53%) respectively. The firm container closure system is LDPE bottle with HDPE caps however, no water loss studies have been conducted by the firm as required for LDPE containers.
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 and finish product testing ?	The firm showed the audit trail reports on API and finish product testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has some remaining quantities of stability batches only.
33	Do you have stability batches kept on real time stability testing?	The firm has completed the accelerated and real time stability testing. The results of study do not conform to the designed specifications.
34	Do you have valid calibration status for the equipment used in the production and analysis of API and Eye Drops?	The firm has valid calibration status for the equipment used in Zithrosan 1% Eye Drops 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, however currently there is no pack of Azithrosan 1% Eye Drops available in the chambers as the study has already been completed.
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. The firm has used 34.26g quantities for manufacturing of three stability batches (1 litre each) of Zithrosan 1% eye drops, from 75 kg API (Azithromycin Dihydrate - tablet grade) imported for production of their registered product, Azithromycin tablets vide invoice No. 201610103 dated 25th October, 2016 from M/S. Ningxia Qiyuan Pharmaceutical Co. Ltd., China.

2. The firm has not performed comparative studies with the innovator product. The innovator product is even not procured by the firm.

3. The firm has manufactured three stability batches for accelerated and real time stability studies of Zithrosan 1% Eye Drops with batch No. 06T, 07T & 08T each of 1Litre quantity. Tablet grade material has been used with 5% overage for manufacturing of eye drops. Literature survey of Azasite 1% ophthalmic solution (innovator product) clearly indicate that the eye drops are in solution form without any overage whereas the firm's product is in suspension form with 5% overage. Moreover, the development protocol of the firm shows that filteration be used for sterilization of the final product however, the filteration process for ophthalmic suspension is inappropriate process. The firm actually has not sterilized the suspension besides the fact that they have conducted the sterility testing in the stability testing program.

4. The firm has developed and validated the method for testing stability batches. However, the method is an isocratic method being validated without the use of impurity standards and forced degradation studies hence the method is non-stability indicating and not validated properly as per guidelines.

5. The method of analysis is not stability indicating. The accelerated stability studies report (Batch # 08T) show the assay results as under:

100.14% (0 month), 107.78% (3 months) and 114.55% (6 months). Hence there is significant change within three months time. The real time stability reports on all three trial batches (06T, 07T and 08T) show that the assay results have crossed the specifications (90.0 % to 110.0%) at 12 months i.e. Batch # 06T (118.81%), 07T (118.94%) and 08T (119.53%) respectively. The firm container closure system is LDPE bottle with HDPE caps however, no water loss studies have been conducted by the firm as required for LDPE containers.

6. The firm has completed the accelerated and real time stability testing. The results of study do not conform to the designed specifications.

Recommendations:

1. Keeping in view the above facts the genuineness / authenticity of stability data submitted by the firm for registration of Zithrosan 1% Eye Drops (Azithromycin as dehydrate) is not verifiable.

2. Since significant change has been found within 03 months in accelerated stability studies, although using non-stability indicated method which clearly indicate that the product is unstable and extrapolated value of degradation will be outside the product specifications (Assay limit 90% - 110%) even using non-stability indicating method.

3. The real time stability studies have also shown out of specification results at 12 months with further increase at 18 months.

4. The firm must re-design / conduct their studies with proper ultra-fine grade API, properly developed formulation and testing program including comparative studies using authentic reference standards of API, impurities and innovator product with stability indicating method under the guidance of proper product development staff.

Decision: **Registration Board deliberated that applied product is me too / generic drug product and thus its product development data is required before sale of drug as done in all other cases. After thorough deliberation, the Board decided to approve the registration of Zithrosan 1% Eye Drops (Azithromycin as dihydrate) based on availability of other generics of applied drug Product. As panel has identified shortcomings thus firm shall repeat product development and registration letter shall be issued after submission of data.**

b. Exemption from onsite verification of stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
991.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera, KPK-Pakistan	ARTRIL Tablets 24mg/26mg Each film coated tablet contains Sacubitril….24mg (Neprilysin inhibitor) Valsartan…..26mg (Angiotensin II Receptor Antagonists) As Sacubitril + Valsartan trisodium hemipentahydrate Firm has claimed Mfg. Specs.	Form-5 Dy. No: 3449 Dated.25-01-2019 Rs.20,000/- (21-01-2019) (Challan # 0788889) As per SRO.	USFDA. ENTRESTO by M/s Novartis Sacuvan tablets 24/26mg of GETZ pharma The firm was granted GMP certificate based on inspection conducted on dated 10-01-2018.

STABILITY STUDY DATA	
Drug	ARTRIL Tablets 24mg/26mg
Name of Manufacturer	M/s Ferozsons Laboratories Limited
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co, Ltd – China No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, P.R. China
API Lot No.	201706001
Description of Pack (Container closure system)	Alu/Alu blister packed in unit carton (1x14's)

Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (month) Real Time: 0, 3, 6 (month)		
Batch No.	SVTab-004	SVTab-005	SVTab-006
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	11-06- 2018	11-06- 2018	11-06- 2018
No. of Batches	03		
Date of Submission	1-2-2019 (Dy. No.4653)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA 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 issued on December 06, 2016 by Nantong Chemical & Medical Industry Association, People's Republic of China is submitted valid till Dec 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 Form 6 issued by ADC Peshawar DRAP along with Form 3, Form 7, packing list, commercial invoice and goods declaration has been submitted. Import quantity: 2 kg **Batch #:** 201706001 **Working standard:** **Batch #:** WS201610001 **Impurities:** Provided **Address of Exporter**: M/s Changzhou Pharmaceutical Factory, 518 Laodong East Road, Changzhou, Jiangsu Province, China **Address of Consignee**: M/s Ferozsons Laboratories Limited. P.O Ferozsons Amangarh, Nowshera, KPK-Pakistan
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: Sacubitril/Valsartan: Tablet II (Paddle) 50, Phosphate Buffer, pH 6.8[degassed], 900,10, 15, 20, 30 and 45		
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 "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS" by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Peshawar) attested Form 6 dated 01/06/2017, Commercial Invoice for 2kg via Invoice # CY117235 dated: 26/06/2017 lot No. 201706001 from M/s. Changzhou Pharmaceutical Factory, 518 Laodong East Road, Changzhou, Jiangsu Province, China vide proper approval from DRAP Office, Peshawar.
3.	Documents for the procurement of reference standard and impurity standards.	The reference and impurity standards were received free of cost with API i.e. Sacubitril + Valsartan trisodium hemipentahydrate.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate issued on December 06, 2016 by Nantong Chemical & Medical Industry Association, People's Republic of China is submitted
5.	Mechanism for Vendor pre-qualification	Firm has submitted SOP "Procedure for induction of new vendor"
6.	Certificate of analysis of the API, reference standards and impurity standards	• **API** Photocopy of COA of Batch No. 201706001 issued by M/s Nantong Chanyoo Pharmatech Co, Ltd – China is submitted. • **Reference standards and impurity standards:** The firm has submitted the copy of COA's of Working Standard and Impurity standards of API provided by the API Manufacturer M/s Nantong Chanyoo Pharmatech Co, Ltd - China
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients used in product development.
8.	List of qualified staff involved in product development with relevant experience.	Firm has submitted list of 10 qualified persons
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of SOP with the title 'Protocol For Development of generic product Artril Tablets (Sacubitril 24mg/Valsartan 26mg) '. **Effective date 18-11-2017.**
10.	Complete batch manufacturing record of three stability batches.	Firm has provided complete batch manufacturing record of all the three batches **ARTRIL Tablets 24mg/26mg**

<table>
<tr><td></td><td></td><td>
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SVTab-004</td><td>2500 Tabs</td><td>29-05-2018</td><td>31-05-2018</td></tr>
<tr><td>SVTab-005</td><td>2500 Tabs</td><td>30-05-2018</td><td>01-06-2018</td></tr>
<tr><td>SVTab-006</td><td>2500 Tabs</td><td>31-05-2018</td><td>01-06-2018</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Artril Tablet 24mg/26mg ; Stability Pack Size : 1 x 14’s)
• SVTab-004: Batch Size : 2500 Tablets
Yield 1596 Tablets (114 Packs),
58 packs (Stability samples) For Accelerated (22 Packs) For Long Term (36 Packs)
56 packs (PD reference samples)
• SVTab-005: Batch Size : 2500 Tablets
Yield 1680 Tablets (120 Packs)
58 packs (Stability samples) For Accelerated (22 Packs) For Long Term (36 Packs)
62 packs (PD reference samples)
• SVTab-006: Batch Size : 2500 Tablets
Yield 1708 Tablets (122 Packs).
58 packs (Stability samples) For Accelerated (22 Packs) For Long Term (36 Packs)
64 packs (PD reference sample)</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period from 30-04-2018 to 29-12-2018.
• Previously Reported in panel inspection:
The firm has stability chamber for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets 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, 18 Months (25°C ± 2°C & 60±5%RH),& stability study reports of 03 batches of Sacubitril/Valsartan Complex (LCZ696) 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 copy of Manufacturer’s COAs and Firm analysis reports 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 (ENTRESTO Tablets).</td></tr>
</table>

<table>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Entresto Tablets manufactured by Novartis Singapore Pharmaceutical.
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Ferozsons Laboratories Limited</th></tr>
<tr><td>Brand name</td><td>Entresto Tablets 24mg/26mg</td><td>Artril Tablets 24mg/26mg</td></tr>
<tr><td>Batch No.</td><td>FX000011</td><td>SVTab-004</td></tr>
<tr><td>Mfg. date</td><td>Exp. 01-2020</td><td>05-2018</td></tr>
</table>
pH buffer 0.01N Solution
pH 4.5 Acetate buffer solution.
pH 6.8 phosphate buffer solution.
• Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports</td></tr>
</table>

Evaluation by PEC:

Sr.#	Deficiency/Observation	Response by Pharma.
i.	• On commercial invoice M/S Changzhou pharmaceutical is mentioned while COA and GMP provided is of M/S Nantong Jiangsu china. Clarification needed.	It is to clarify that as per provided invoice M/s Changzhou Pharmaceutical Factory – China is a Beneficiary's name and Manufacturer name is Nantong Chanyoo Pharmatech Co, Ltd – China Moreover STATEMENT that Nantong Chanyoo Pharmatech Co, Ltd –China is wholly owned subsidiary of M/s Changzhou Pharmaceutical Factory – China is also provided
ii.	Stability of API is on 25°C ± 2°C & 60±5%RH	Stability studies report of API as per condition of Zone IV-A is submitted
iii.	Extra peak on some chromatograms I.e. SVT-004-603.icd, SVT-004-602.icd	The extra peaks in some chromatograms are of solvent Solvent pH 1.2 is used as media to conduct comparative dissolution profile Chromatograms showing only solvent pH 1.2 peaks obtain are also provided.
iv.	Comparative dissolution raw data sheets	Provided
v.	The initiation date is 6/2018 but the date on chromatograms are of 2017. (sample: QC NO.R-8937 &**2017**09011) Clarification is needed	The chromatograms are not of 2017. Whereas the sample: QC NO.R-8937 & 201709011 is sample identification number and not the date. Moreover each and every chromatogram has its own date at which analysis was conducted. Chromatograms with highlighted dates are provided

Decision: Registration Board decided to approve registration of "ARTRIL Tablets 24mg/26mg (Sacubitril….24mg & Valsartan…..26mg) by M/s Ferozsons Laboratories Limited, Nowshera, KPK-Pakistan, with the change in brand name. 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 GMP Inspection Report Date & Remarks
992.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera, KPK-Pakistan	ARTRIL Tablets 97mg/103mg Each film coated tablet contains Sacubitril….97mg (Neprilysin inhibitor) Valsartan…..103mg (Angiotensin II Receptor Antagonists) As Sacubitril + Valsartan trisodium hemipentahydrate Firm has claimed Mfg. Specs.	Form-5 Dy. No: 3450 Dated.25/01/2019 Rs.20,000/- (Challan #0788890) As per SRO	USFDA. ENTRESTO by M/s Novartis Not applicable The firm was granted GMP certificate based on inspection conducted on dated 10-01-2018.

STABILITY STUDY DATA			
Drug	ARTRIL Tablets 97mg/103mg		
Name of Manufacturer	M/s Ferozsons Laboratories Limited		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co, Ltd – China No.2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong, Jiangsu Province 226407, P.R.China		
API Lot No.	201706001		
Description of Pack (Container closure system)	Alu/Alu blister packed in unit carton (1x14's)		
Stability Storage Condition	Real time : 30°C ± 2°C / 75% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (month) Real Time: 0, 3,6 (month)		
Batch No.	SVTab-007	SVTab-008	SVTab-009
Batch Size	950 tablets	950 tablets	950 tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	29-05- 2018	29-05- 2018	29-05- 2018
No. of Batches	03		
Date of Submission	01-2-2019 (Dy. No.4656)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA 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 issued on December 06, 2016 by Nantong Chemical & Medical Industry Association, People's Republic of China is submitted.
3.	Protocols followed for conduction of stability study	Yes

	and details of tests.	
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 issued by ADC Peshawar DRAP along with Form 3, Form 7, packing list, commercial invoice and goods declaration has been submitted. Import quantity: 2 kg **Batch #:** 201706001 **Working standard:** **Batch #:** WS201610001 **Impurities:** Provided **Address of Exporter**: M/s Changzhou Pharmaceutical Factory, 518 Laodong East Road, Changzhou, Jiangsu Province, China **Address of Consignee**: M/s Ferozsons Laboratories Limited. P.O Ferozsons Amangarh, Nowshera, KPK-Pakistan
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.	Firm has referred to onsite inspection report of their product "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS" by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Peshawar) attested Form 6 dated 01/06/2017, Commercial Invoice for 2kg via Invoice # CY117235 dated: 26/06/2017 lot No. 201706001 from M/s. Changzhou Pharmaceutical Factory, 518 Laodong East Road, Changzhou, Jiangsu Province, China vide proper approval from DRAP Office, Peshawar.
3.	Documents for the procurement of reference standard and impurity standards.	The reference and impurity standards were received free of cost with API i.e. Sacubitril + Valsartan trisodium hemipentahydrate. Copy of packing list and commercial invoice provided
4.	Approval of API/ DML/GMP certificate of API manufacturer	Copy of GMP Certificate issued on December 06, 2016 by Nantong Chemical & Medical Industry Association, People's Republic of China

<table>
<tr><td></td><td>issued by regulatory authority of country of origin.</td><td>is submitted</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted SOP “Procedure for induction of new vendor”</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• API
Photocopy of COA of Batch No. 201706001 issued by M/s Nantong Chanyoo Pharmatech Co, Ltd – China is submitted.
• Reference standards and impurity standards:
The firm has submitted the copy of COA’s of Working Standard and Impurity standards of API provided by the API Manufacturer M/s Nantong Chanyoo Pharmatech Co, Ltd - China</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 10 qualified persons</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 ‘Protocol For Development of generic product Artril Tablets (Sacubitril 97mg/Valsartan 103mg) ’.
Effective date 18-11-2017.</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
<table>
<tr><th colspan="4">ARTRIL Tablets 97mg/103mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SVTab-007</td><td>950 Tabs</td><td>14-05-2018</td><td>17-05-2018</td></tr>
<tr><td>SVTab-008</td><td>950 Tabs</td><td>18-05-2018</td><td>19-05-2018</td></tr>
<tr><td>SVTab-009</td><td>950 Tabs</td><td>20-05-2018</td><td>21-05-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Artril Tablet 97mg/103mg ; Stability Pack Size : 1 x 14’s)
• SVTab-007: Batch Size : 950 Tablets
Yield 560 Tablets (40 Packs),
34 packs (Stability samples) For Accelerated (15 Packs) For Long Term (19 Packs)
6 packs (PD reference samples)

• SVTab-008: Batch Size : 950 Tablets
Yield 658 Tablets (47 Packs)
34 packs (Stability samples) For Accelerated (15 Packs) For Long Term (19 Packs)
13 packs (PD reference samples)

• SVTab-009: Batch Size : 950 Tablets
Yield 644 Tablets (46 Packs).
34 packs (Stability samples) For Accelerated (15 Packs) For Long Term (19 Packs)
12 packs (PD reference sample)</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</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period from 30-04-2018 to 29-12-2018.
• Previously Reported in panel inspection:</td></tr>
</table>

<table>
<tr><td></td><td>accelerated)</td><td>The firm has stability chamber for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets 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, 18 Months (25°C ± 2°C & 60±5%RH),& stability study reports of 03 batches of Sacubitril/Valsartan Complex (LCZ696) 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 copy of Manufacturer’s COAs and Firm analysis reports 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 (ENTRESTO Tablets).</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Entresto Tablets manufactured by Novartis Singapore Pharmaceutical.
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Ferozsons Laboratories Limited</th></tr>
<tr><td>Brand name</td><td>Entresto Tablets 97mg/103mg</td><td>Artril Tablets 97mg/103mg</td></tr>
<tr><td>Batch No.</td><td>F0005</td><td>SVTab-008</td></tr>
<tr><td>Mfg. date</td><td>Exp. 12-2018</td><td>05-2018</td></tr>
</table></td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports</td></tr>
</table>

Evaluation by PEC:

Sr.#	Deficiency/Observation	Response by Pharma.
i.	• On commercial invoice M/S Changzhou pharmaceutical is mentioned while COA and GMP provided is of M/S Nantong Jiangsu china. Clarification needed.	It is to clarify that as per provided invoice M/s Changzhou Pharmaceutical Factory – China is a Beneficiary’s name and Manufacturer name is Nantong Chanyoo Pharmatech Co, Ltd – China Moreover STATEMENT that Nantong Chanyoo Pharmatech Co, Ltd –China is wholly owned subsidiary of M/s Changzhou Pharmaceutical Factory – China is also provided
i.	Stability of API is on 25°C ± 2°C & 60±5%RH	Stability studies report of API as per condition of Zone IV-A is submitted
i.	Extra peak on some chromatograms I.e. SVT-004-603.icd, SVT-004-602.icd	The extra peaks in some chromatograms are of solvent Solvent pH 1.2 is used as media to conduct comparative dissolution profile Chromatograms showing only solvent pH 1.2 peaks obtain are also provided.
’.	Comparative dissolution raw data sheets	Provided

v.	The initiation date is 6/2018 but the date on chromatograms are of 2017. (sample: QC NO.R-8937 &**2017**09011) Clarification is needed	The chromatograms are not of 2017. Whereas the sample: QC NO.R-8937 & 201709011 is sample identification number and not the date. Moreover each and every chromatogram has its own date at which analysis was conducted. Chromatograms with highlighted dates are provided.

Decision: Registration Board decided to approve registration of "ARTRIL Tablets 97mg/103mg (Sacubitril….97mg & Valsartan…..103mg) by M/s Ferozsons Laboratories Limited, Nowshera, KPK-Pakistan, with the change in brand name. 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 GMP Inspection Report Date & Remarks
993.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera, KPK-Pakistan	SOLYXA Tablets 5mg Each film coated tablet contains Solifenacin succinate….5mg (Antimuscarinics) Firm has claimed Mfg. Specs.	Form-5 Dy. No: 6563 Dated.14-2-19 Rs.20,000/- (22-May-2017) As per SRO	USFDA. VESICARE by M/s Astellas Pharma USA Fenaso of Highnoon Laboratories Ltd. The firm was granted GMP certificate based on inspection conducted on dated 10-01-2018.

STABILITY STUDY DATA

Drug	SOLYXA Tablets 5mg		
Name of Manufacturer	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera, KPK-Pakistan		
Manufacturer of API	M/s Jubilant Generics Limited – India Plot # 18, 56, 57 and 58, KIADB Industrial Area, Nanjangud, Mysore, Karnataka 571302, India		
API Lot No.	7SLF317008		
Description of Pack (Container closure system)	Alu/Alu blister packed in unit carton (1x10's)		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (month) Real Time: 0, 3,6 (month)		
Batch No.	SSTab-004	SSTab-005	SSTab-006
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	04-2018	04-2018	04-2018

Date of Initiation	23-05- 2018	23-05- 2018	23-05- 2018
No. of Batches	03		
Date of Submission	25-1-2019 (Dy. No.3445)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from Jubilant Generics Limited – 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 (DCD/CR-125/SPL.CL-/2018-19) issued on April 23, 2018 by Office of the Drugs Controller For the State of Karnataka, Palace Road, Bangalore-560 001-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.	Copy of Form 6 issued by ADC Peshawar DRAP along with copy of DRAP acknowledgement regarding intimation of receiving of **Solifenacin succinate** 150gm along with working standard 250mg and impurities standards 5x10mg from **M/s Jubilant Generics Limited - India** **API Batch #:** 7SLF317008 **Working standard Batch #:** SLF/R0019/045 **Impurities:** Provided **Address of Manufacturer**: M/s Jubilant Generics Limited – India Plot # 18, 56, 57 and 58, KIADB Industrial Area, Nanjangud, Mysore, Karnataka 571302, India **Address of Consignee**: M/s Ferozsons Laboratories Limited. P.O Ferozsons Amangarh, Nowshera, KPK-Pakistan
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.	Firm has referred to onsite inspection report of their product "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS"

<table>
<tr><td></td><td></td><td>by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed
HPLC is 21 CFR compliant
Audit trails of the test reports were available.
Related manufacturing area equipment's personals and utilities were found GMP compliant.</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 Form 6 # 00425/2017-DRAP(P)/1550 dated: 01-06-2017 issued by ADC Peshawar DRAP along with copy of DRAP acknowledgement dated: 06-10-2017, regarding intimation of receiving of Solifenacin succinate 150gm along with working standard 250mg and impurities standards 5x10mg from M/s Jubilant Generics Limited – India</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The reference and impurity standards were received free of cost with API i.e. Solifenacin succinate. Copy of DRAP acknowledgement regarding intimation of receiving of Solifenacin succinate 150gm along with working standard 250mg and impurities standards 5x10mg from M/s Jubilant Generics Limited – India is attached.</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 on April 23, 2018 by Office of the Drugs Controller For the State of Karnataka, Palace Road, Bangalore-560 001-India is submitted</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted SOP "Procedure for induction of new vendor"</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>API
Photocopy of COA of Batch No. 7SLF317008 issued by Jubilant Generics Limited – India is submitted.
Reference standards and impurity standards:
The firm has submitted the copy of COA's of Working Standard and Impurity standards of API provided by the API Manufacturer M/s Jubilant Generics Limited – India</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 10 qualified persons</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 'Protocol For Development of generic product Solyxa 5mg and 10mg Tablets (Solifenacin succinate) '.
Effective date 16-03-2018.</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
<table>
<tr><th colspan="4">SOLYXA Tablets 5mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SSTab-004</td><td>2500 Tabs</td><td>02-04-2018</td><td>09-04-2018</td></tr>
<tr><td>SSTab-005</td><td>2500 Tabs</td><td>02-04-2018</td><td>09-04-2018</td></tr>
<tr><td>SSTab-006</td><td>2500 Tabs</td><td>02-04-2018</td><td>09-04-2018</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Solyxa Tablet 5mg; Stability Pack Size : 1 x 10's)
• SSTab-004: Batch Size : 2500 Tablets
Yield 2130 Tablets (213 Packs),
65 packs (Stability samples) For Accelerated (26 Packs) For Long Term (39 Packs)
148 packs (PD reference samples)
• SSTab-005: Batch Size : 2500 Tablets
Yield 2130 Tablets (213 Packs),
65 packs (Stability samples) For Accelerated (26 Packs) For Long Term (39 Packs)
148 packs (PD reference samples)
• SSTab-006: Batch Size : 2500 Tablets
Yield 2050 Tablets (205 Packs),
65 packs (Stability samples) For Accelerated (26 Packs) For Long Term (39 Packs)
140 packs (PD reference samples)</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period from
11-05-2018 to 11-01-2019
• Previously Reported in panel inspection:
The firm has stability chamber for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets 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, 60 Months (30°C ± 2°C & 65±5%RH),& stability study reports of 03 batches of Solifenacin succinate from M/s Jubilant Generics Limited – India</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of Manufacturer's COA's and Firm analysis reports 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 (VESICARE Tablets).</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Vesicare Tablets manufactured by Astellas Pharma US, Inc.
<table><tr><th>Feature</th><th>Reference Product</th><th>Product of Ferozsons Laboratories Limited</th></tr><tr><td>Brand name</td><td>Vesicare Tablets 5mg</td><td>Solyxa Tablets 5mg</td></tr><tr><td>Batch No.</td><td>D1700004</td><td>SSTab-004</td></tr><tr><td>Mfg. date</td><td>Exp. 12-2019</td><td>04-2018</td></tr></table></td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports</td></tr>
</table>

Evaluation by PEC:

Sr.#	Deficiency/Observation	Response by Pharma.
i.	The formula used to calculate the assay and dissolution is not correct. Clarification is required for this regard.	Firm claims that, As already mentioned in method of analysis the concentration of sample & standard used in the assay and dissolution is same. So, that's why the peak area of standard and sample was considered to calculate the percentage of assay and dissolution Formula Peak area of sample %age = ---------- x 100 Peak area of standard USP Reference is provided
i.	Clarification is required, regarding inverted peaks in assay and dissolution analysis (Dissolution: e.g. Sample ID: B No. SSTAB-005) Assay (Sample ID: B No. SSTAB-005.103.lcd)	Firm responded that these inverted peaks or extra peaks are of pure solvent peak used in the analysis method provided. Moreover, the analytical method validation study. In which the specificity is clarifying the solvent peaks
i.	Clarification is required, regarding variation in run time of chromatograms in assay and dissolution analysis. (Dissolution is on 5.5 min in chromatograms in volume 2/6) and 7 minutes in chromatograms in volume 6/6)	Firm reply that, "The difference of run time in dissolution profile study is due to different media used and during study possibility of some extra peaks may be elute. Due to this reason, run time increased to make sure the elution of these extra peaks if any. That's why the run time increases up to one min more in the comparative dissolution profile study. As this is only the study of our product dissolution behavior in different media with innovator product".
'.	Why baseline is not stable in comparative dissolution chromatograms (e.g. in case of dissolution pH 4.5). Justify	The comparative dissolution study is conducted in different pH media as recommended by the USP. The column behaves differently in different medias as a general rule. In case of Acetate buffer media pH 4.5 the base line is stable and some peaks of the media are observed as a normal consequence. This is followed by the distinct peak of the active Solifenacin succinate which is reproducible in all the runs. Therefore there is no observed deviation.

Decision:Deferred for consideration of case on its turn, as applied formulation is a Me Too product, for which submission of stability studies are not required at present.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
994.	M/s Ferozsons Laboratories Limited P.O Ferozsons, Amangarh, Nowshera, KPK-Pakistan	SOLYXA Tablets 10mg Each film coated tablet contains Solifenacin succinate….10mg (Antimuscarinics) Firm has claimed Mfg. Specs.	Form-5 Dy. No: 22841 Dated.15-8-2018 Rs.20,000/- (22-May-2017) Duplicate As per SRO	USFDA. VESICARE by M/s Astellas Pharma USA Fenaso of Highnoon Laboratories Ltd. The firm was granted GMP certificate based on inspection conducted on dated 10-01-2018.

STABILITY STUDY DATA			
Drug	SOLYXA Tablets 10mg		
Name of Manufacturer	M/s Ferozsons Laboratories Limited		
Manufacturer of API	M/s Jubilant Generics Limited – India Plot # 18, 56, 57 and 58, KIADB Industrial Area, Nanjangud, Mysore, Karnataka 571302, India		
API Lot No.	7SLF317008		
Description of Pack (Container closure system)	Alu/Alu blister packed in unit carton (1x10's)		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (month) Real Time: 0, 3,6 (month)		
Batch No.	SSTab-001	SSTab-002	SSTab-003
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	16-05- 2018	16-05- 2018	16-05- 2018
No. of Batches	03		
Date of Submission	25-1-19 (Dy. No.3346)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from Jubilant Generics Limited – 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 on April 23, 2018 by Office of the Drugs Controller For the State of Karnataka, Palace Road, Bangalore-560 001-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.	Copy of Form 6 issued by ADC Peshawar DRAP along with copy of DRAP acknowledgement regarding intimation of receiving of **Solifenacin succinate** 150gm along with working standard 250mg and impurities standards 5x10mg from **M/s Jubilant Generics Limited - India** **API Batch #:** 7SLF317008 **Working standard Batch #:** SLF/R0019/045 **Impurities:** Provided **Address of Manufacturer**: M/s Jubilant Generics Limited – India Plot # 18, 56, 57 and 58, KIADB Industrial Area, Nanjangud, Mysore, Karnataka 571302,

		India **Address of Consignee**: M/s Ferozsons Laboratories Limited. P.O Ferozsons Amangarh, Nowshera, KPK-Pakistan
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.	Firm has referred to onsite inspection report of their product "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS" by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted Copy of Form 6 # 00425/2017-DRAP(P)/1550 dated: 01-06-2017 issued by ADC Peshawar DRAP along with copy of DRAP acknowledgement dated: 06-10-2017, regarding intimation of receiving of **Solifenacin succinate** 150gm along with working standard 250mg and impurities standards 5x10mg from **M/s Jubilant Generics Limited – India**
3.	Documents for the procurement of reference standard and impurity standards.	The reference and impurity standards were received free of cost with API i.e. Solifenacin succinate. Copy of DRAP acknowledgement regarding intimation of receiving of **Solifenacin succinate** 150gm along with working standard 250mg and impurities standards 5x10mg from **M/s Jubilant Generics Limited – India** is attached.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate issued on April 23, 2018 by Office of the Drugs Controller For the State of Karnataka, Palace Road, Bangalore-560 001-India is submitted
5.	Mechanism for Vendor pre-qualification	Firm has submitted SOP "Procedure for induction of new vendor"
6.	Certificate of analysis of the API, reference standards and impurity standards	• **API** Photocopy of COA of Batch No. 7SLF317008 issued by Jubilant Generics Limited – India is submitted. • **Reference standards and impurity standards:** The firm has submitted the copy of COA's of Working Standard and Impurity standards of API provided by the API Manufacturer M/s Jubilant Generics Limited – India.

<table>
<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 10 qualified persons</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 ‘Protocol For Development of generic product Solyxa 5mg and 10mg Tablets (Solifenacin succinate) ’.
Effective date 16-03-2018.</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
<table>
<tr><th colspan="4">SOLYXA Tablets 10mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SSTab-001</td><td>2500 Tabs</td><td>02-04-2018</td><td>07-04-2018</td></tr>
<tr><td>SSTab-002</td><td>2500 Tabs</td><td>02-04-2018</td><td>07-04-2018</td></tr>
<tr><td>SSTab-003</td><td>2500 Tabs</td><td>02-04-2018</td><td>07-04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Solyxa Tablet 10mg; Stability Pack Size : 1 x 10’s)
• SSTab-001: Batch Size : 2500 Tablets
Yield 1980 Tablets (198 Packs),
65 packs (Stability samples) For Accelerated (25 Packs) For Long Term (40 Packs)
133 packs (PD reference samples)
• SSTab-002: Batch Size : 2500 Tablets
Yield 1930 Tablets (193 Packs),
65 packs (Stability samples) For Accelerated (25 Packs) For Long Term (40 Packs)
128 packs (PD reference samples)
• SSTab-003: Batch Size : 2500 Tablets
Yield 1830 Tablets (183 Packs),
65 packs (Stability samples) For Accelerated (25 Packs) For Long Term (40 Packs)
118 packs (PD reference samples)</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period from
11-05-2018 to 11-01-2019
• Previously Reported in panel inspection:
The firm has stability chamber for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets 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, 60 Months (30°C ± 2°C & 65±5%RH),& stability study reports of 03 batches of Solifenacin succinate from M/s Jubilant Generics Limited – India</td></tr>
</table>

16.	Analysis reports for excipients used.	The firm has submitted copy of Manufacturer's COA's and Firm analysis reports 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 (VESICARE Tablets).
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile with the reference product Vesicare Tablets manufactured by Astellas Pharma US, Inc.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports

Feature	**Reference Product**	**Product of Ferozsons Laboratories Limited**
Brand name	Vesicare Tablets 10mg	Solyxa Tablets 10mg
Batch No.	E1700232	SSTab-001
Mfg. date	Exp. 02-2020	04-2018

Evaluation by PEC:

Sr.#	**Deficiency/Observation**	**Response by Pharma.**
i.	The formula used to calculate the assay and dissolution is not correct. Clarification is required for this regard.	Firm claims that, As already mentioned in method of analysis the concentration of sample & standard used in the assay and dissolution is same. So, that's why the peak area of standard and sample was considered to calculate the percentage of assay and dissolution Formula Peak area of sample %age = ---------- x 100 Peak area of standard USP Reference is provided
i.	Clarification is required, regarding inverted peaks in assay and dissolution analysis (Dissolution: e.g. Sample ID: B No. SSTAB-005) Assay (Sample ID: B No. SSTAB-005.103.lcd)	Firm responded that these inverted peaks or extra peaks are of pure solvent peak used in the analysis method provided. Moreover, the analytical method validation study. In which the specificity is clarifying the solvent peaks
i.	Clarification is required, regarding variation in run time of chromatograms in assay and dissolution analysis. (Dissolution is on 5.5 min in chromatograms in volume 2/6) and 7 minutes in chromatograms in volume 6/6)	Firm reply that, "The difference of run time in dissolution profile study is due to different media used and during study possibility of some extra peaks may be elute. Due to this reason, run time increased to make sure the elution of these extra peaks if any. That's why the run time increases up to one min more in the comparative dissolution profile study. As this is only the study of our product dissolution behavior in different media with innovator product".
'.	Why baseline is not stable in comparative dissolution chromatograms (e.g. in case of dissolution pH 4.5). Justify	The comparative dissolution study is conducted in different pH media as recommended by the USP. The column behaves differently in different medias as a general rule. In case of Acetate buffer media pH 4.5 the base line is stable and some peaks of the media are observed as a normal consequence. This is followed by the distinct peak of the active Solifenacin succinate which is reproducible in all the runs. Therefore there is no observed deviation.

Decision: Deferred for consideration of case on its turn, as applied formulation is a Me Too product, for which submission of stability studies are not required at present.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
995.	M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore	Valpas 400/100 tablets Each Film Coated Tablet contains: Sofosbuvir…… ….400mg Velpatasvir…100 mg Anti-viral drug	Form 5D Dy. No. 2009 (Duplicate dossier) 13/01/2017 Fee 50000/- (Challan # 0568772) Duplicate Pack Size 14's tablets Price /- per pack	Epclusa400mg/100mg Tablet (Canada) Last inspection report Dated **27/09/2018** is attached which confirms the good level of GMP compliance.

STABILITY STUDY DATA			
Drug	Valpas 400/100 tablets		
Name of Manufacturer	**M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore**		
Manufacturer of API	**Sofosbuvir (**Optimus Drugs Pvt Ltd, India**)** **Velpatasvir (**Optrix Laboratories Pvt Ltd**)**		
API Lot No.	**Sofosbuvir** (OP-GLD/10/17/073) **Velpatasvir (**OT-VCP/002/79)		
Description of Pack (Container closure system)	Alu – Alu blister		
Stability Storage Condition	**Real Time:** 30'C ± 2'C / 65% ± 5%RH **Accelerated:**40'C ±2'C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:**0,3,6,9, 12, 18, 24 (Months) **Accelerated:** 0,3 & 6 (Months)		
Batch No.	**RD 18123**	**RD 18124**	**RD 18125**
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	06-2018	06-2018	06-2018
No. of Batches	**03 batches**		
Date of Submission	5-3-2019 (Dy. No.11568)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from: **Sofosbuvir:** Optimus Drugs Pvt Ltd, 1-2-11/1, Above SBI bank st no.2,Kakatiya Nagar, Habsiguda Hyderabad-500007, Telangana India **Velpatasvir:** Optrix Laboratories Pvt Ltd, Survey no 147,Ramalingampally (V),

		Bommalaramaram (M), Yadadri Bhuvanagirl (D)-508126, Telangana India
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: **Sofosbuvir:** (#2021/A3/2018) issued to Optimus Drugs Pvt Ltd, 1-2-11/1, Above SBI bank st no.2,Kakatiya Nagar, Habsiguda Hyderabad-500007, Telangana India issued by drug control administration Gov of telangana valid till 21-5-2020. **Velpatasvir:** (#5109/A3/2018) issued to Optrix Laboratories Pvt Ltd, Survey no 147,Ramalingampally (V), Bommalaramaram (M), Yadadri Bhuvanagirl(D)-508126, Telangana India drug control administration Gov of telangana valid till 4-9-2020.
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 commercial invoice has been submitted issued by ADC, DRAP. **Sofosbuvir:** Import quantity: 250 kg **Reference standard:** NA **Impurities:** Not provided **Velpatasvir:** Import quantity: 2 kg **Reference standard:** NA **Impurities:** Not 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		
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 conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 1. HPLC is 21 CFR compliant 2. Audit trails of the test reports were available. 3. Related manufacturing area equipment's personals and utilities were found GMP compliant.

2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sofosbuvir:** The firm has submitted photocopies of ADC (Lahore) attested, dated 31-10-2017, Commercial Invoice for 250 Kg via Invoice # 293/EXP dated: 24-10-2017 Lot No. OP-GLD/10/17/071 from M/s. Optimus Drugs (Pvt) Ltd., India Survey No. 239 & 240, Dothigudem (V), Pochampally (M), Yadadri – Bhuvanagiri (D), 508284, Telangana, India. vide proper approval from DRAP Office, Lahore. **Velpatasvir:** The firm has submitted photocopies of ADC (Lahore) attested, dated 21-02-2018, Commercial Invoice for 2Kg via Invoice # OT069/EXP dated: 25-01-2018 Lot No. OT-VCP/002/79 from M/s. Optrix Laboratories (Pvt) Ltd., India, Survey No. 147, Ramalingampally (V), Bommalaramaram (M), Yadadri – Bhuvanagiri (D), Telangana, India vide proper approval from DRAP Office, Lahore.
3.	Documents for the procurement of reference standard and impurity standards.	The reference standards were received free of cost with API Sofosbuvir & Velpatasvir. Therefore, no separate procuring documents available.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sofosbuvir** copy of GMP Certificate issued on 02 January, 2017 by Drugs Control Administration, Government of Telangana, India. **Velpatasvir** copy of GMP Certificate issued on 12th July, 2017 by Drugs Control Administration, Government of Telangana, India.
5.	Mechanism for Vendor pre-qualification	Firm has submitted Vendor Qualification Flow Chart.
6.	Certificate of analysis of the API, reference standards and impurity standards	• **Sofosbuvir API:** Photocopy of COA of Batch No. OP-GLD/10/17/073 issued by M/s Optimus Drugs Pvt Ltd, India is submitted. 1. Reference standards: The firm has submitted the copy of Reference Standards (Sofosbuvir) Batch No. OP-SFS/RS1402, provided by the API Manufacturer - M/s Optimus Drugs Pvt Ltd, India • **Velpatasvir API:** Photocopy of COA of Batch No. OT-VCP/002/79 issued by M/s Optrix Laboratories Pvt Ltd, India is submitted. 2. Reference standards: The firm has submitted the copy of Reference Standards (Velpatasvir) Batch No. OT-VCP/S1/003/01, provided by the API Manufacturer - M/s Optrix Laboratories Pvt Ltd, India
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients used in product development.
8.	List of qualified staff involved in product development with relevant experience.	Firm has submitted list of 06 qualified person working in R&D section
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of generalized SOP with the title **'Product Design & Development'.** **Effective Date: 10th April, 2017**

<table>
<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
<table>
<tr><th colspan="4">SOFOSBUVIR - VELPATASVIR 400-100MG TABLET</th></tr>
<tr><th>BATCH NO.</th><th>BATCH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr>
<tr><td>RD-18123</td><td>900 Tabs</td><td>06-06-2018</td><td>06-06-2018</td></tr>
<tr><td>RD-18124</td><td>900 Tabs</td><td>06-06-2018</td><td>06-06-2018</td></tr>
<tr><td>RD-18125</td><td>900 Tabs</td><td>06-06-2018</td><td>06-06-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sofosbuvir-Velpatasvir 400-100mg Tablet; Stability Pack Size : 4 x 7's)
• RD-18123: Batch Size : 900 Tablets
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 02 pack are remaining Accelerated and 13 Packs remaining Real Time.
• RD-18124: Batch Size : 900 Tablets
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 02 pack are remaining Accelerated and 13 Packs remaining Real Time.
• RD-18125: Batch Size : 900 Tablets
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 02 pack are remaining Accelerated and 13 Packs remaining Real Time.</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Sofosbuvir: The firm has submitted copy of Long Term 24 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches of Sofosbuvir from M/s Optimus Drugs (Pvt) Ltd., India.
Velpatasvir: The firm has submitted copy of Accelerated 03 Months (40°C ± 2°C & 75±5%RH) and Long Term 03 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches of Velpatasvir from M/s Optrix Laboratories (Pvt) Ltd., India.</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 Drug-excipients compatibility studies</td></tr>
</table>

18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile with the reference product Epclusa™ 400mg/100mg Tablet, Patheon Inc. Mississauga, ON L5N 7K9 Canada.

FEATURE	REFERENCE PRODUCT	PRODUCT OF HIGHNOON
BRAND NAME	Epclusa™ 400/100mg Tablet	Sofosbuvir–Velpatasvir 400/100mg Tablets
BATCH NO.	YPPGD3	RD-18124
MFG. / EXPIRY DATE	Mfg. Date: 07-2017 Exp. Date: 07-2020	Mfg. Date: 06-2018 Exp. Date: 06-2020

Test was performed at:

i. 1.2N Hydrochloric Acid Solution
ii. pH 4.5 Acetate buffer solution.
iii. pH 7.4 phosphate buffer solution.

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.

Evaluation by PEC:

S #	Short comings	Response of Firm
..	COA of impurity standards are required	The related substance in API and FPP are evaluated by the validated method provided by API manufacturer (Optimus drug pvt Ltd). In this method the related substance (RP isomers) are calculated by area normalization method which does not required impurity standard. For identification of known impurity (RP isomer) the relative retention time of the impurity are used. The relative retention time of impurity is about 0.95 with reference to sofosbuvir retention time.
2.	Valid GMP certificate is required as Photocopy of GMP Certificate Sofosbuvir: (# 11980/A3/2016) issued to Optimus Drugs Pvt Ltd, was valid up to 1-2019.	Valid GMP certificate of Sofosbuvir: (# 2021/A3/2018) issued to Optimus Drugs Pvt Ltd, valid up to 21-5-2020 is provided.
3.	Valid GMP certificate is required as Photocopy of GMP Certificate Velpatasvir: (#8340/A3/2017) issued by Optrix Laboratories Pvt Ltd, was valid up to 7-2018.	Valid GMP certificate of Velpatasvir: (#5109/A3/2018) issued to Optimus Drugs Pvt Ltd, valid up to 4-9-2020 is provided.
4.	The innovators finish product testing including tests for microbial contents. Justify the exemption of these tests	The microbiological testing is not performed on trial batches the first three commercial validation batches will be subject to microbiology testing and subsequently every 5th commercial batch of solid dosage form will be tested
5.	Stability studies reports on conditions of Zone IV-A for API conducted by API manufacturer is required.	**For API:** The firm has submitted copy Long Term 03 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches On **query** they submitted that according to WHO technical report series Regarding real time stability study storage conditions for long term stability study is 25°C ± 2°C / 60% ± 5% RH or 30°C ± 2°C / 65% ± 5% RH "which is determined by the climatic condition under which API is intended to be stored". ICH guideline also supported that statement that "*therefore the climatic conditions for long term stability study can be selected based on the intended storage conditions of the*

		API. Manufacturer recommended the storage of valpatesvir API at 25°C ± 2°C / 60% ± 5% RH and at highnoon the raw material store is maintained at 25°C ± 2°C / 60% ± 5% RH therefore we request you to accept the stability at 25°C ± 2°C / 60% ± 5% RH

Decision: Registration Board decided to defer the case for submission of complete stability studies for three batches of API either as per zone IV-A conditions as only copy of Long Term 03 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches are submitted OR Justification on scientific basis that whether an API with stability studies at (250C ±20C & 60 ±5% RH.) be used to prepare a FPP which has to be stored 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 GMP Inspection Report Date & Remarks
996.	M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore	Sacuva 50 mg tablets Each Film Coated Tablet contains: Sacubitril ….24 mg Valsartan …..26mg Angiotensin II Receptor Blockers	Form 5D Dy. No. 384 10/11/2016 Fee 50000/- (challan # 0568768) 07/11/2016 Pack Size 14's, 20's,30's, 60's tablets Price /- per pack	Entresto (FDA) Last inspection report Dated **27/09/2018** is attached which confirms the good level of GMP compliance.

STABILITY STUDY DATA

Drug	Sacuva 50 mg		
Name of Manufacturer	M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore		
Manufacturer of API	**(Sacubitril/Valsartan)** Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China		
API Lot No.	**57317060103**		
Description of Pack (Container closure system)	Alu – Alu blister		
Stability Storage Condition	**Real Time:** 30'C ± 2'C / 65% ± 5%RH **Accelerated:**40'C ±2'C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months (9 month data provided) **Accelerated:** 6 Months		
Frequency	**Real Time:**0,3,6,9, 12, 18, 24 (Months) **Accelerated:** 0,3 & 6 (Months)		
Batch No.	**RD 18002**	**RD 18003**	**RD 18004**
Batch Size	3000 tablets	3000 tablets	3000 tablets
Manufacturing Date	01/18	01/18	01/18
Date of Initiation	03/18	03/18	03/18
No. of Batches	**03 batches**		
Date of Submission	11-2-19 (Dy. No.18779)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from M/s Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China 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 (# GD20160649) issued by China Food and Drug Administration People's Republic of China is submitted valid till 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 commercial invoice has been submitted issued by ADC, DRAP. Import quantity: 2 kg **Reference standard:** 50 mg #170801 **Working standard:** 100 mg **Batch #:** 18-WS-04 **Impurities:** Not 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
. Risk assessment report of sacubitril/valsartan is provided about NDMA . Stability Study of API is on 25 C and 30 both . Detection at 254. With 8 minutes time Check it with protocol . Check protocol according to USFDA dissolution or not? . Some of the excipient are different from innovator e.g. innovators is using copovidone
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 conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 4. HPLC is 21 CFR compliant 5. Audit trails of the test reports were available. 6. Related manufacturing area equipment's personals and utilities were found GMP compliant.

<table>
<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 photocopies of ADC (Lahore) attested, dated 19-10-2017, Commercial Invoice for 2Kg via Invoice # RIS17079 dated: 28-09-2017 Lot No. 57317060103 from M/s. Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China vide proper approval from DRAP Office, Lahore</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The reference standards were received free of cost with API Secubitril/Valsartan. Therefore, no separate procuring documents available.
Reference standard: 50 mg #170801
Working standard: 100 mg
Batch #: 18-WS-04
Impurities: Not provided</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 (# GD20160649) issued by China Food and Drug Administration People’s Republic of China is submitted valid till 2021</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted Vendor Qualification Flow Chart.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Sacubitril / Valsartan API:
Photocopy of COA of Batch No. 57317060103 issued by M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China is submitted.
Reference standards:
The firm has submitted the copy of Reference Standards (Sacubitril & Valsartan) Batch No. 170801, provided by the API Manufacturer - M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China</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 06 qualified person working in R&D 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>The firm has submitted copy of generalized SOP with the title ‘Product Design & Development’.
Effective Date: 10th April, 2017</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
<table>
<tr><th colspan="4">Sacuva 50mg Tablets</th></tr>
<tr><th>BATCH NO.</th><th>BACH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr>
<tr><td>RD-18002</td><td>3,000 Tabs</td><td>09-01-2018</td><td>12-01-2018</td></tr>
<tr><td>RD-18003</td><td>3,000 Tabs</td><td>09-01-2018</td><td>12-01-2018</td></tr>
<tr><td>RD-18024</td><td>3,000 Tabs</td><td>29-01-2018</td><td>05-02-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sacuva 50mg Tablets; Stability Pack Size : 2 x 10’s)
• RD-18002: Batch Size : 3,000 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.
• RD-18003: Batch Size : 3,000 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14</td></tr>
</table>

		Packs), out of which 01 pack are remaining **Accelerated** and 07 Packs remaining **Real Time.** • **RD-18024: Batch Size : 3,000 Tablets** 19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining **Accelerated** and 07 Packs remaining **Real Time.**
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.
13.	Method used for analysis of API along with COA.	Firm has provided the method used for analysis of API along with its certificate of analysis
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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 09 months Real Time Stability Data.
15.	Reports of stability studies of API from manufacturer.	**SACUBITRIL:** 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) **and Intermediate 12 Months** (30°C ± 2°C & 75±5%RH) & stability study reports 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 copy of COAs for the excipients used in the applied formulation.
17.	Drug-excipients compatibility studies.	The firm has submitted Drug-excipients compatibility studies
18.	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile with the reference product Entresto 50mg Tablet, Novertis Pharma, Switzerland.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.

FEATURE	REFERENCE PRODUCT	PRODUCT OF HIGHNOON
BRAND NAME	Entresto 50mg Tabs	Sacuva 50mg Tabs
BATCH NO.	TN690	RD-18024
MFG. / EXPIRY DATE	Mfg. Date: 12-2017 Exp. Date: 11-2019	Mfg. Date: 01-2018 Exp. Date: 01-2020

Evaluation by PEC:

- The firm has submitted copy of generalized SOP with the title 'Product Design & Development'.Provide complete stability protocols along with detail protocols of dissolution method and assay methods.
- Why on stability 24.3 and 25.7 is mentioned but reference is of 24 ad 26
- In protocol batch number is mentioned as 18024 but in protocol its 8005?
- Impurity standard details?
- Reference of last onsite panel inspection for instant dosage form conducted during last two years

S #	Short comings	Response of Firm
..	Provide complete stability protocols along with detail protocols of trail batches and testing methods e.g. dissolution method and assay methods.	The stability and report have been submitted
..	COA and import documents of	The related substance in API and FPP are evaluated by the

	impurity standards are required	validated method provided by API manufacturer Zuhai Rundu pharmaceuticals co Ltd. In this method the related substance are calculated by *area normalization method* which does not required impurity standard. For identification of impurity the relative retention time of the impurity are used. The relative retention time of impurity B is about 0.7 and impurity C is about 5 with reference to valsartan retention time (6 min)
3.	Some of the excipient are different from innovator e.g. innovators is using copovidone which is not used in applied product. Clarification is needed.	Firm replied that they are also using Co-povidone by the name of Kollidone VA 64
4.	Reference to approval of one (01) similar dosage form by Registration Board on the basis of which you are claiming exemption from verification of authenticity of submitted stability data	Last onsite inspection conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 7. HPLC is 21 CFR compliant 8. Audit trails of the test reports were available. Related manufacturing area equipment's personals and utilities were found GMP compliant.

Decision: Registration Board decided to approve registration of "Sacuva 50 mg tablets (Sacubitril 24 mg, Valsartan …..26mg) by M/s M/s Highnoon Laboratories, 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.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
997.	**M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore**	Sacuva 100 mg tablets Each Film Coated Tablet contains: Sacubitril ….49mg Valsartan …..51mg Angiotensin II Receptor Blockers	Form 5D Dy. No. 385 10/11/2016 Fee 50000/- (#0568770) 07/11/2016 Pack Size 14's tablets Price /- per pack	Entresto (FDA) Last inspection report Dated **27/09/2018** is attached which confirms the good level of GMP compliance.

STABILITY STUDY DATA	
Drug	Sacuva 100 mg
Name of Manufacturer	**M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore**
Manufacturer of API	**(Sacubitril/Valsartan)** Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China
API Lot No.	**57317060103**
Description of Pack	Alu – Alu blister

(Container closure system)			
Stability Storage Condition	**Real Time:** 30'C ± 2'C / 65% ± 5%RH **Accelerated:**40'C ±2'C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months (9 month data provided) **Accelerated:** 6 Months		
Frequency	**Real Time:**0,3,6,9, 12, 18, 24 (Months) **Accelerated:** 0,3 & 6 (Months)		
Batch No.	**RD 18005**	**RD 18006**	**RD 18043**
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	01/18	01/18	01/18
Date of Initiation	03/18	03/18	03/18
No. of Batches	**03 batches**		
Date of Submission	11-2-19 (Dy. No.5909)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from M/s Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China 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 (# GD20160649) issued by China Food and Drug Administration People's Republic of China is submitted valid till 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 commercial invoice has been submitted issued by ADC, DRAP. Import quantity: 2 kg Reference standard: 50 mg #170801 Working standard: 100 mg Batch #: 18-WS-04 Impurities: Not 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

. Risk assessment report of sacubitril/valsartan is provided about NDMA
. Stability Study of API is on 25 oC and 30 both
. Detection at 254. With 8 minutes time Check it with protocol
. Check protocol according to USFDA dissolution or not?
. Some of the excipient are different from innovator e.g. innovators is using copovidone

<table>
<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>Last onsite inspection conducted on 1st January, 2019 for following products
Nebvax (Nebivolo + Valsartan) 5/80mg Tablet
Daplozmet 5/850mg Tablet
Daplozmet 5/1000mg Tablet
According to the report following important points were confirmed
HPLC is 21 CFR compliant
Audit trails of the test reports were available.
Related manufacturing area equipment's personals and utilities were found GMP compliant.</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 photocopies of ADC (Lahore) attested, dated 19-10-2017, Commercial Invoice for 2Kg via Invoice # RIS17079 dated: 28-09-2017 Lot No. 57317060103 from M/s. Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China vide proper approval from DRAP Office, Lahore.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The reference standards were received free of cost with API Secubitril/Valsartan. Therefore, no separate procuring documents available.</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 (# GD20160649) issued by China Food and Drug Administration People's Republic of China is submitted valid till 2021</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted Vendor Qualification Flow Chart.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Sacubitril / Valsartan API:
Photocopy of COA of Batch No. 57317060103 issued by M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China is submitted.
Reference standards:
The firm has submitted the copy of Reference Standards (Sacubitril & Valsartan) Batch No. 170801, provided by the API Manufacturer - M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China</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 06 qualified person working in R&D section</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 generalized SOP with the title 'Product Design & Development'.
Effective Date: 10th April, 2017</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
<table>
<tr><th colspan="4">Sacuva 100mg Tablets</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>RD-18005</td><td>1,500 Tabs</td><td>18-01-2018</td><td>22-01-2018</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>RD-18006</td><td>1,500 Tabs</td><td>18-01-2018</td><td>23-01-2018</td></tr>
<tr><td>RD-18043</td><td>1,500 Tabs</td><td>29-01-2018</td><td>12-02-2018</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sacuva 100mg Tablets; Stability Pack Size : 2 x 10's)
• RD-18005: Batch Size : 1,500 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.
• RD-18006: Batch Size : 1,500 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.
• RD-18043: Batch Size : 1,500 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 09 months Real Time Stability Data.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>SACUBITRIL: 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) and Intermediate 12 Months (30°C ± 2°C & 75±5%RH) & stability study reports of 03 batches of Sacubitril/Valsartan from M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China</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 Drug-excipients compatibility studies</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Entresto 100mg Tablet, Novertis Pharma, Switzerland
<table>
<tr><th>FEATURE</th><th>REFERENCE PRODUCT</th><th>PRODUCT OF HIGHNOON</th></tr>
<tr><td>BRAND NAME</td><td>Entresto 100mg Tabs</td><td>Sacuva 100mg Tabs</td></tr>
<tr><td>BATCH NO.</td><td>TP182</td><td>RD-18043</td></tr>
<tr><td>MFG. / EXPIRY DATE</td><td>Mfg. Date: 12-2017
Exp. Date: 11-2019</td><td>Mfg. Date: 01-2018
Exp. Date: 01-2020</td></tr>
</table>
</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.</td></tr>
<tr><td colspan="3">Evaluation by PEC:
• Provide complete stability protocols along with detail protocols of dissolution method and assay methods.
• Why on stability 24.3 and 25.7 is mentioned but reference is of 24 ad 26
• In protocol batch number is mentioned as 18024 but in protocol its 8005.</td></tr>
</table>

S #	Short comings	Response of Firm
.	Provide complete stability protocols along with detail protocols of trail batches and testing methods e.g. dissolution method and assay methods.	The stability and report have been submitted
.	COA and import documents of impurity standards are required	The related substance in API and FPP are evaluated by the validated method provided by API manufacturer Zuhai Rundu pharmaceuticals co ltd.In this method the related substance are calculated by area normalization method which does not required impurity standard. For identification of impurity the relative retention time of the impurity are used. The relative retention time of impurity B is about 0.7 and impurity C is about 5 with reference to valsartan retention time (6 min)
.	Some of the excipient are different from innovator e.g. innovators is using copovidone which is not used in applied product. Clarification is needed.	Firm replied that they are also using Copovidoneby the name of Kollidone VA 64
.	Reference to approval of one (01) similar dosage form by Registration Board on the basis of which you are claiming exemption from verification of authenticity of submitted stability data	Last onsite inspection conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 1. HPLC is 21 CFR compliant 2. Audit trails of the test reports were available. Related manufacturing area equipment's personals and utilities were found GMP compliant.

•

Decision: Registration Board decided to approve registration of "Sacuva 100 mg tablets (Sacubitril 49 mg, Valsartan 51mg) by M/s Highnoon Laboratories, 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.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
998.	**M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore**	Sacuva 200 mg tablets Each Film Coated Tablet contains: Sacubitril ….97mg Valsartan …..103mg Angiotensin II Receptor Blockers	Form 5D Dy. No. 383 10/11/2016 Fee 50000/- (#0568769) 10/11/2016 Pack Size 14's tablets Price /- per pack	Entresto (FDA) Last inspection report Dated **27/09/2018** is attached which confirms the good level of GMP compliance.

STABILITY STUDY DATA			
Drug	Sacuva 200 mg		
Name of Manufacturer	**M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore**		
Manufacturer of API	**(Sacubitril/Valsartan)** Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China		
API Lot No.	**57317060103**		
Description of Pack (Container closure system)	Alu – Alu blister		
Stability Storage Condition	**Real Time:** 30'C ± 2'C / 65% ± 5%RH **Accelerated:**40'C ±2'C / 75% ± 5%RH		
Time Period	**Real Time:** 24 Months (9 month data provided) **Accelerated:** 6 Months		
Frequency	**Real Time:**0,3,6,9, 12, 18, 24 (Months) **Accelerated:** 0,3 & 6 (Months)		
Batch No.	**RD 18008**	**RD 18009**	**RD 18044**
Batch Size	750 tablets	750 tablets	750 tablets
Manufacturing Date	01/18	01/18	01/18
Date of Initiation	03/18	03/18	03/18
No. of Batches	**03 batches**		
Date of Submission	11-2-19 (Dy. No.5909)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from M/s Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China 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 (# GD20160649) issued by China Food and Drug Administration People's Republic of China is submitted valid till 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 commercial invoice has been submitted issued by ADC, DRAP. Import quantity: 2 kg Reference standard: 50 mg #170801 Working standard: 100 mg Batch #: 18-WS-04 Impurities: Not 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

. Risk assessment report of sacubitril/valsartan is provided about NDMA
. Stability Study of API is on 25 oC and 30 both
. Detection at 254. With 8 minutes time Check it with protocol
. protocol according to USFDA
. Some of the excipient are different from innovator e.g. innovators is using copovidone

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 conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 1. HPLC is 21 CFR compliant 2. Audit trails of the test reports were available. 3. Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Lahore) attested, dated 19-10-2017, Commercial Invoice for 2Kg via Invoice # RIS17079 dated: 28-09-2017 Lot No. 57317060103 from M/s. Zhuhai Rundu Pharmaceutical Co. Ltd China No.6, North Airport Road, Sanzao Town, Jinwan District, Guangdong, China vide proper approval from DRAP Office, Lahore.
3.	Documents for the procurement of reference standard and impurity standards.	The reference standards were received free of cost with API Secubitril/Valsartan. Therefore, no separate procuring documents available.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate (# GD20160649) issued by China Food and Drug Administration People's Republic of China is submitted valid till 2021
5.	Mechanism for Vendor pre-qualification	Firm has submitted Vendor Qualification Flow Chart.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Sacubitril / Valsartan API: Photocopy of COA of Batch No. 57317060103 issued by M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China is submitted. Reference standards: The firm has submitted the copy of Reference Standards (Sacubitril & Valsartan) Batch No. 170801, provided by the API Manufacturer - M/s Zhuhai Rundu Pharmaceutical Co., Ltd., China
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients used in product development.
8.	List of qualified staff involved in product development with relevant experience.	Firm has submitted list of 06 qualified person working in R&D section

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<tr><td>RD-18009</td><td>750 Tabs</td><td>18-01-2018</td><td>23-01-2018</td></tr>
<tr><td>RD-18044</td><td>750 Tabs</td><td>29-01-2018</td><td>12-02-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sacuva 200mg Tablets; Stability Pack Size : 2 x 7's)
• RD-18008: Batch Size : 750 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.
• RD-18009: Batch Size : 750 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.
• RD-18044: Batch Size : 750 Tablets
19 Packs placed on stability (Accelerated: 05 Packs, Real Time : 14 Packs), out of which 01 pack are remaining Accelerated and 07 Packs remaining Real Time.</td></tr>
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<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Highnoon</th></tr>
<tr><td>Brand Name</td><td>Entresto 200mg Tabs</td><td>Sacuva 200mg Tabs</td></tr>
</table></td></tr>
</table>

		BATCH NO.	TN272	RD-18044
		MFG. / EXPIRY DATE	Mfg. Date: 12-2017 Exp. Date: 11-2019	Mfg. Date: 01-2018 Exp. Date: 01-2020
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.		

Evaluation by PEC:

- Provide complete stability protocols along with detail protocols of dissolution method and assay methods.
- Why on stability 24.3 and 25.7 is mentioned but reference is of 24 ad 26

S #	Short comings	Response of Firm
..	Provide complete stability protocols along with detail protocols of trail batches and testing methods e.g. dissolution method and assay methods.	The stability and report have been submitted
2.	COA and import documents of impurity standards are required	The related substance in API and FPP are evaluated by the validated method provided by API manufacturer Zuhai Rundu pharmaceuticals co ltd.In this method the related substance are calculated by area normalization method which does not required impurity standard. For identification of impurity the relative retention time of the impurity are used. The relative retention time of impurity B is about 0.7 and impurity C is about 5 with reference to valsartan retention time (6 min)
3.	Some of the excipient are different from innovator e.g. innovators is using copovidone which is not used in applied product. Clarification is needed.	Firm replied that they are also using Copovidoneby the name of Kollidone VA 64
4.	Reference to approval of one (01) similar dosage form by Registration Board on the basis of which you are claiming exemption from verification of authenticity of submitted stability data	Last onsite inspection conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 4. HPLC is 21 CFR compliant 5. Audit trails of the test reports were available. Related manufacturing area equipment's personals and utilities were found GMP compliant.

Decision: Registration Board decided to approve registration of "Sacuva 200 mg tablets (Sacubitril 97 mg, Valsartan …..103mg) by M/s M/s Highnoon Laboratories, 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.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
999.	M/s Crystolite Pharmaceuticals, plot #1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.	Dasone 5% gel Each g of gel contains: Dapsone……5% w/w (Anti-Infective) In-house Specifications	Form-5-D Dy. No: 910 Dated: 11-4-16 Rs.50,000/- (8/4/2016) (Challan # 0532804) As per SRO	ACZONE of Aqua Pharma (USFDA) Last inspection was conducted on 17-10-2017 concluding good compliance

STABILITY STUDY DATA

Drug	Dasone 5% gel		
Name of Manufacturer	M/s Crystolite Pharmaceuticals, plot #1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.		
Manufacturer of API	**Dapsone:** M/S Chongqing Huapont shengchem Pharma. co. Ltd. No. 666, Rongjun road, Nanjin Avenue, Hechuandistrict Chongqing, China		
API Lot No.	**Dapsone:** DAP-20170701		
Description of Pack (Container closure system)	15 gm and 30 gm plastic tube		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (month) Real Time: 0, 3,6, 9 (month)		
Batch No.	034T17	035T17	036T17
Batch Size	0.6 kg (60 packs)	0.6 kg (60 packs)	0.6 kg (60 packs)
Manufacturing Date	10-2017	10-2017	10-2017
Date of Initiation	15-12- 2017	15-12- 2017	15-12- 2017
No. of Batches	03		
Date of Submission	23-5-2018 (Dy. No.18779)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA from Chongqing Huapont shengchem Pharma. co. Ltd. No. 666, Rongjun road, Nanjin Avenue, Hechuandistrict Chongqing, China 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 Chongqing (City) Food and Drug Administration People's Republic of China is submitted valid till 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.	**Dapsone:** Copy of commercial invoice has been submitted issued by ADC, Islamabad DRAP. Import quantity: 400 g **Working standard:** 100 mg **Batch #:** DAP-WS-20170514 **Impurities:** Not 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

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 "Halovate cream, lotion, ointment" (Halobetasol) and Plaiglo cream which was conducted on 22-August 2017 and was presented in 271th meeting of Registration board. Registration Board decided to approve registration. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Islamabad) attested Commercial Invoice for 400gm via Invoice # HP2017914 dated: 14/09/2017 lot No. DAP-20170701 from Chongqing Huapont shengchem Pharma. co. Ltd. No. 666, Rongjun road, Nanjin Avenue, Hechuandistrict Chongqing, Chinavide proper approval from DRAP Office, Islamabad.
3.	Documents for the procurement of reference standard and impurity standards.	The reference and impurity standards were received free of cost with API. Therefore no procuring documents available. But undertaking from Chongqing Huapont Pharmaceuticals co Ltd is provided that sample is provided along with API
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate issued by Chongqing Food and Drug Administration People's Republic of China is submitted valid till 2020. (Certificate # CQ20150003)
5.	Mechanism for Vendor pre-qualification	Firm has submitted SOPs for vendor evaluation and performance monitoring
6.	Certificate of analysis of the API, reference standards and impurity standards	• **Dapsone API:** Photocopy of COA of Batch No. DAP-20170701 issued by Chongqing Huapont shengchem Pharma. co. Ltd. Chongqing, China is submitted. • **Reference standards and impurity standards:** The firm has submitted the copy of Working Standard (Batch # DAP-WS-20170514), **Reference Standard and impurity standards of API were not provided**
7.	Documents for the procurement of excipients used in product	Firm has submitted documents for procurement of excipients used in product development.

<table>
<tr><td></td><td>development?</td><td></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 6 qualified person, 3working in 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 generalized SOP for stability studies and product development protocols.</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
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>034T17</td><td>0.6 kg (60 packs)</td><td>10- 2017</td></tr>
<tr><td>035T17</td><td>0.6 kg (60 packs)</td><td>10- 2017</td></tr>
<tr><td>036T17</td><td>0.6 kg (60 packs)</td><td>10- 2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Dapsone 5% gel ; Batch #: 034T17
Stability Pack Size : 35 packs
Remaining Packs after 9 months of real time stability: 17 packs
Stability Pack Size : 18 packs
Remaining Packs after 6 months of accelerated stability: 3 packs
Batch #: 035T17
Stability Pack Size : 33 packs
Remaining Packs after 9 months of real time stability: 15 packs
Stability Pack Size : 18 packs
Remaining Packs after 6 months of accelerated stability: 3 packs
Batch #: 036T17
Stability Pack Size : 35 packs
Remaining Packs after 9 months of real time stability: 17 packs
Stability Pack Size : 18 packs
Remaining Packs after 6 months of accelerated stability: 3 packs</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 record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months stability data (Accelerated). & 9 months real Time</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Dapsone: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) , long term, 36 Months (30°C ± 2°C & 75±5%RH),& stability study reports of 03 batches of Dapsone from Chongqing Huapont shengchem Pharma. co. Ltd. Chongqing, China</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</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm claims that as it’s a gel dosage form comparative studies is not needed</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports</td></tr>
</table>

	on product testing.	

Evaluation by PEC:

Deficiency/Observation	Response by Pharma.
The firm do not submitted the copy of Working Standards, Reference Standard and impurity standards of API provided by the API Manufacturer	Working standard COA was submitted, other are still needed.
Firm has not submitted SOPs for vendor evaluation and performance monitoring	Provided
Drug-excipients compatibility studies.	Firm has not submitted Drug-excipients compatibility studies & has referred to Innovator Product.
Evidence of fee of 50,000/-	Provided
Description of Pack (Container closure system)	Provided
GMP certificate is of city not province	Copy of GMP Certificate issued by Chongqing (City) Food and Drug Administration People's Republic of China is submitted valid till 2020 is again submitted

Decision: Registration Board decided to approve registration of "Dasone 5% gel by M/s Crystolite Pharmaceuticals, Islamabad, and 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 GMP Inspection Report Date & Remarks
1000.	M/s Crystolite Pharmaceuticals, plot #1 & 2, Street S-2, National Industrial Zone, Rawat, Islamabad.	Dasone 7.5 % gel Each g of gel contains: Dapsone……7.5% w/w (Anti-Infective) In-house Specifications	Form-5-D Dy. No: 909 Dated: 11-4-2016 Rs.50,000/- (8/4/2016) (Challan # 0532805)	ACZONE of Aqua Pharma (USFDA) Last inspection was conducted on 17-10-2017 concluding good compliance

STABILITY STUDY DATA

Drug	Dasone 7.5% gel		
Name of Manufacturer	M/s Crystolite Pharmaceuticals, plot #1 & 2, Street S-2, National Industrial Zone, Rawat, and Islamabad.		
Manufacturer of API	**Dapsone:** M/S Chongqing Huapont shengchem Pharma. co. Ltd. No. 666, Rongjun road, Nanjin Avenue, Hechuandistrict Chongqing, China		
API Lot No.	**Dapsone:** DAP-20170701		
Description of Pack (Container closure system)	15 gm and 30 gm plastic tube		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,6 (month) Real Time: 0, 3,6, 9 (month)		
Batch No.	034T17	035T17	036T17
Batch Size	0.6 kg (60 packs)	0.6 kg (60 packs)	0.6 kg (60 packs)
Manufacturing Date	12-2017	12-2017	12-2017

Date of Initiation	15-12- 2017	15-12- 2017	15-12- 2017
No. of Batches	03		
Date of Submission	23-5-2018 (Dy. No.18779)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from Chongqing Huapont shengchem Pharma. co. Ltd. No. 666, Rongjun road, Nanjin Avenue, Hechuandistrict Chongqing, China submitted has different batch number then the batch number on commercial invoice.
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 Chongqing Food and Drug Administration People's Republic of China is submitted valid till 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.	**Dapsone:** Copy of commercial invoice has been submitted issued by ADC, Islamabad DRAP. Import quantity: 400 g **Working standard:** 100 mg **Batch #:** DAP-WS-20170514 **Impurities:** Not 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

i. Comparative Dissolution in: pH 1.2 HCl solution, pH 4.5 acetate buffer and pH 6.8 phosphate buffer solution
ii. Calculations of F2 Value is missing in comparative dissolution
iii. Impurities details provided (valsartan B C, COA provided)
iv. Detection at 254 nm
v. Run time: 15 min
vi. The test performed are pH, physical appearance, identification and assay by HPLC (50 volume of acetonitrile and 50 of water) a max (254 m),column 250x4.6 mm and flow rate is 1 ml/min

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 "Halovate cream, lotion, ointment" (Halobetasol) and Plaiglo cream which was conducted on 22-August 2017 and was presented in 271th meeting of Registration board. Registration Board decided to approve registration. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and

<table>
<tr><td></td><td></td><td>utilities were found GMP compliant.</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 photocopies of ADC (Islamabad) attested Commercial Invoice for 400gm via Invoice # HP2017914 dated: 14/09/2017 lot No. DAP-20170701 from Chongqing Huapont shengchem Pharma. co. Ltd. No. 666, Rongjun road, Nanjin Avenue, Hechuandistrict Chongqing, Chinavide proper approval from DRAP Office, Islamabad.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The reference and impurity standards were received free of cost with API. Therefore no procuring documents available. But undertaking from Chongqing Huapont Pharmaceuticals co Ltd is provided that sample is provided along with API</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 Chongqing Food and Drug Administration People’s Republic of China is submitted valid till 2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>Firm has submitted SOPs for vendor evaluation and performance monitoring</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Dapsone API:
Photocopy of COA of Batch No. DAP-20170701 issued by Chongqing Huapont shengchem Pharma. co. Ltd. Chongqing, China is submitted.
• Reference standards and impurity standards:
The firm submitted the copy of Working Standards, But Reference Standard and impurity standards of API is not provided</td></tr>
<tr><td>7.</td><td>Documents for 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 6 qualified person, 3working in 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 generalized SOP for stability studies and product development protocols.</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
<table>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th></tr>
<tr><td>037T17</td><td>0.6 kg (60 packs)</td><td>15-12- 2017</td></tr>
<tr><td>038T17</td><td>0.6 kg (60 packs)</td><td>15-12- 2017</td></tr>
<tr><td>039T17</td><td>0.6 kg (60 packs)</td><td>15-12- 2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Dapsone 7.5% gel ; Batch #: 037T17
Stability Pack Size : 35 packs
Remaining Packs after 9 months of real time stability: 17 packs
Stability Pack Size : 18 packs
Remaining Packs after 6 months of accelerated stability: 3 packs
Batch #: 038T17
Stability Pack Size : 36 packs
Remaining Packs after 9 months of real time stability: 18 packs
Stability Pack Size : 18 packs
Remaining Packs after 6 months of accelerated stability: 3 packs
Batch #: 039T17
Stability Pack Size : 37 packs</td></tr>
</table>

		Remaining Packs after 9 months of real time stability: 19 packs Stability Pack Size : 18 packs Remaining Packs after 6 months of accelerated stability: 3 packs
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.
13.	Method used for analysis of API along with COA.	Firm has provided the method used for analysis of API along with its certificate of analysis
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 and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months stability data (Accelerated). & 9 months real Time
15.	Reports of stability studies of API from manufacturer.	**Dapsone:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) , **long term, 36 Months** (30°C ± 2°C & 75±5%RH),& stability study reports of 03 batches of Dapsone from Chongqing Huapont shengchem Pharma. co. Ltd. Chongqing, China
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
18.	Record of comparative dissolution data.	Firm claims that as it's a gel dosage form comparative studies is not needed
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports

Evaluation by PEC:

Deficiency/Observation	**Response by Pharma.**
The firm do not submitted the copy of Working Standards, Reference Standard and impurity standards of API provided by the API Manufacturer	Working standard COA was submitted, other are still needed.
Firm has not submitted SOPs for vendor evaluation and performance monitoring	Provided
Drug-excipients compatibility studies.	The firm has not submitted Drug-excipients compatibility studies and has referred to the Innovator Product
Evidence of fee of 50,000/-	Provided
Description of Pack (Container closure system)	Provided

Decision: Registration Board decided to approve registration of "Dasone 7.5% gel by M/s Crystolite Pharmaceuticals, Islamabad, and 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 GMP Inspection Report Date & Remarks
1001.	M/ s Dyson Research Laboratories (Pvt.) Ltd. 28th KM Ferozpur Road, Lahore.	Esonap 20/500 Tablet Each coated tablet contains: Naproxen…….500 mg Esomperazole (as Meagnesium) .....20 mg Anti-inflammatory and Anti-rheumatic Manufacturer's Specifications.	Form 5 Dairy No. Duplicate dossier Dated 4-2-2019. Rs.8000/- (Duplicate) Dated 25-May-2011 12000 absent	Vimovo Tablet 20/500 by Horizone Pharma USA Panel inspection conducted on 08-12-2018 recommended for grant of GMPcertificate.

STABILITY STUDY DATA			
Drug	Esonap 500/20 mg Tablet		
Name of Manufacturer	M/ s Dyson Research Laboratories (Pvt.) Ltd. 28th KM Ferozpur Road, Lahore.		
Manufacturer of API	**Naproxen:** M/S Zhejiang Tianxin pharmaceutical co., Ltd No 215 Fengze road, Tiantai Zheiang 317200, China		
	Esomeprazole as magnesium trihydrate: M/s Everest Organics Ltd. Aroor Village, Sadasivpet Mandal, Medak District – 502291 Telangana India		
API Lot No.	**Naproxen:** NX1611329 **Esomeprazole:** ESM/E-326/16		
Description of Pack (Container closure system)	Alu / Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time : 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, 1, 2,3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial#03	Trial#04	Trial#05
Batch Size	1000 Tablet	1000 Tablet	1000 Tablet
Manufacturing Date	02/2018	02/2018	02/2018
Date of Initiation	20-03-2018	20-03-2018	20-03-2018
No. of Batches	03		
Date of Submission	4872 (4/2/2019)		

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.	**Naproxen:** Copy of GMP certificate (Certificate No. ZJ20170020) for M/S Zhejiang Tianxin Pharmaceutical corporation Limited China issued by Zheijang province Food & Drug Administration, valid upto 3/28/2022. **Esomeprazole:** Copy of GMP certificate (Certificate No. ZJ20170020) for M/s Everest Organics Ltd. Aroor Village, Sadasivpet Mandal, Medak District – 502291 Telangana India issued by Zheijang province Food & Drug Administration, valid up to 3/28/2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted following: •Copy of form 3 confirming license to import of API's •Copy of form 7 (Batch Certification) •ADC attested copy of commercial invoice
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 was according to USFDA. Details are as under

Dissolution 1 (naproxen at core), Dissolution 2 (naproxen at coating stage),Dissolution 3 (esomeprazole at coating stage)

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 products Daclavir Tablet 30 & 60 mg (Daclatasvir as Dihydrochloride), Ledipasvir + Sofosbuvir and Sofosbuvir Tablets which was conducted on 06th February, 2018 and was presented in 279th meeting of Registration Board held on 29-31st January, 2018.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Firm has submitted following: • Permission letter for import of API Vide Ref No. 12494/2016/DRAP (A-IV) Quantity: Naproxen: 6.562 kg, Esomeprazole: 334.5 gm • Copy of form 3 confirming license to import of API's • Copy of form 7 (Batch Certification) • ADC (Lahore) attested copy of commercial invoice
3.	Documents for the procurement of reference standard and impurity standards.	**Esomeprazole:** Firm has submitted copy of invoice for the Purchase of reference standard & Impurity standard i-e 100 mg Omeprazole Sulphone (Impurity-D) & Omeprazole N-Oxide (Impurity-E) **Naproxen:** Firm has submitted exemption of submission of

		procurement of impurity standard of naproxen s they claim that API manufacturer claim no impurity in there COA as per USP.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate **Esomeprazole Magnesium Trihydrate**: Everest Organic limited Certificate No. L.Dis.No.3600/E(S)/TS/2018 Dated 30-06-2018 Issued by: Drugs control Administration Government of Telangana, India. **Naproxen Base:** Zheijiang Tianxin pharma Certificate # No. ZJ20140007 Dated 27-01-2014 Issued by: State Food and Drug Administration China
5.	Mechanism for Vendor pre-qualification	Firm has submitted copy of vendor evaluation documents form and vendor evaluation report
6.	Certificate of analysis of the API, reference standards and impurity standards	**Esomeprazole Magnesium Trihydrate**: Firm has submitted COA of API and reference standard and impurity standards (Impurity D and E) **Naproxen:** Firm has submitted COA of API **reference standard missing** **Impurity: Firm submitted exemption of submission of procurement of impurity standard as they claim that API manufacturer claim no impurity in there COA as per USP.**
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Technical staff (6 person) list including R&D was provided by firm.
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	Firm has submitted authorized protocols/SOPs for the development & testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all three batches
11.	Record of remaining quantities of stability batches.	**T03:** 540 Tablets (70 Acc, 470 Real Time) **T04:** 530 Tablets (60 Acc, 470 Real Time) **T05:** 530 Tablets (60 Acc, 470 Real Time)
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 of temperature and humidity monitoring of stability, stability chambers (real time and Chambers (real time and accelerated)
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API
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 submitted method of analysis of FPP and complete record of testing of stability complete record of testing of stability batches along batches (i.e. chromatograms, lab reports, with chromatograms, lab reports, raw data sheets etc.)
15.	Reports of stability studies of API from manufacturer.	**Esomeprazole:** Firm has submitted both accelerated (40°C ± 2°C &75±5%RH)

		stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches **Naproxen:** Firm has submitted both accelerated (40°C ± 2°C &75±5%RH) stability studies & long term **(25°C ± 2°C & 65±5%RH)** stability studies reports of three batches
16.	Analysis reports for excipients used.	Form has provided COA and testing reports of excipients used
17.	Drug-excipients compatibility studies.	Firm has used the same excipients as that used by innovator Firm has conducted compatibility study of drug-excipients using FTIR spectra.
18.	Record of comparative dissolution data.	Comparative dissolution with innovator was performed and record was available.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has 21CFR compliant software installed on HPLC 20-A Schimadzu

Evaluation by PEC:

Sr.#	Deficiency/Observation	Response by Pharma.
i.	Clarification regarding exemption of submission of procurement of impurity standard of naproxen on the base of the claim that API manufacturer claim no impurity in there COA as per USP but the provided COA mentioned two impurities i.e. impurity O, L	Naproxen API manufacturer complies specification of both USP and BP as per COA. So as per USP specification there are no impurities as mentioned in the COA. We also followed USP specifications containing no impurities. COA of Naproxen is provided
ii.	Certificate of analysis of the Naproxen, reference standards prove of its procurement	CAO of Naproxen reference standard is provided and we received RS along with the API so there is no separate invoice of it.
iii.	USP and API manufacturer performs naproxen API, assay with HPLC Justify the use of titration method for testing of API by applicant.	USP performs assay by titration method, reference. In COA of Naproxen API, manufacturer did not mention HPLC method of assay**. (Note:** Testing of Naproxen by manufacturer on HPLC does not make firm bound to adopt the same because questioned article is a USP monograph).
iv.	API stability of naproxen at conditions of zone IV-A	Provided. **Firm has submitted both accelerated (40°C ± 2°C &75±5%RH) stability studies & long term (25°C ± 2°C & 65±5%RH) stability studies reports of three batches on query they provide the stability studies on long term (30°C ± 2°C & 65±5%RH) by API manufacturer**
v.	Details method of comparative dissolution. Why it's not performed on 3 mediums?	Comparative dissolution as required by standard is not applicable to modified or delayed release tablet dosage form. Secondly firm has conducted and provided data of comparative dissolution of Naproxen in acidic medium and in pH 6.8 buffer.

Decision: Registration Board decided to approve registration of "Esonap 20/500 Tablet (Naproxen…….500 mg & Esomperazole (as Meagnesium) ...20 mg) by M/s Dyson Research Laboratories (Pvt.)Ltd. 28th KM Ferozpur Road, 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.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1002.	**M/s Helix Pharma (Pvt.) Ltd. A-56, S.I.T.E, Manghopir road, Karachi.**	OMO / ASPER TABLETS 81mg/40mg Each Film coated delayed released tablet contains: Aspirin (Delayed-release)….81 mg Omeprazole (Immediate release)……. 40 mg (PPI and analgesic) Firm has claimed Mfg. Specs. (Helix Pharma)	Form-5D Dy. No. 1576 4-05-2017 Rs. 50,000/- (Challan # 0587028) Pack Size: 10's , 20's & 30's (As per PRC)	YOSPRALA Tablets 81mg/40mg by Arelez Pharmaceuticals US Inc. Not applicable GMP compliant dated 24/09/2018

STABILITY STUDY DATA			
Drug	OMO / ASPER TABLETS 81mg/40mg (Aspirin + Omeprazole)		
Name of Manufacturer	Helix Pharma (Pvt.) Ltd., Karachi.		
Manufacturer of API	**Aspirin:** M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA.		
	Omeprazole: M/s Metrochem API Pvt. Ltd, INDIA.		
API Lot No.	**Aspirin:** CA1709001 **Omeprazole:** OMP/1709477		
Description of Pack (Container closure system)	Alu / Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time : 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, 3 ,6 (Months) Real Time : 0, 3 ,6 (Months)		
Batch No.	TF 001	TF 002	TF 003
Batch Size	500 Tablets	500 Tablets	500 Tablets
Manufacturing Date	01 - 2018	01 – 2018	01 – 2018
Date of Initiation	02-02-2018	02-02-2018	02-02-2018
No. of Batches	03		
Date of Submission	4212 (30/1/2019)		

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.	**Aspirin:** Firm has submitted copy of GMP Certificate (#SN20150132) of manufacturer "JQC (Huayin) Pharmaceutical Co., Ltd. CHINA." issued by SFDA, China which is valid till 29/04/2020. **Omeprazole:** Firm has submitted copy GMP Certificate of manufacturer "Metrochem API Pvt Ltd, Plot No: 62/C/6, Pipeline road, Phase-I, IDA, Jeedimetla INDIA" issued by Drugs Control Administration, Government of Telangara , 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 (Karachi) attested invoice 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

- Dissolution is according to USFDA.

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter No. 1857 (R&I) dated 15-01-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 276th Meeting.

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 RAMELTON Tablets 8mg (Ramelteon) in its 273rd Meeting. o Date of Inspection: 18-08-2017. o The HPLC is 21CFR Compliant. o Audit trail on the testing reports of ―Ramelton (Ramelteon) Tablets 8mg were available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 30-11-2017, Commercial Invoice attestation on dated 30/11/2017 for 0.8 Kg of Aspirin **Omeprazole:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 24-10-2017, Commercial Invoice attestation on dated 24/10/2017 for 2.0 Kg of Omeprazole.
3.	Documents for the procurement of reference standard and impurity standards.	• The firm has submitted analytical reports/COA of reference standard & impurity standards. Reference/Working standard: omeprazole and aspirin provided Impurity standard: omeprazole and aspirin provided

<table>
<tr><td></td><td></td><td>• The firm has clarified 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>Aspirin: Firm has submitted copy of GMP Certificate of manufacturer "JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA." issued by SFDA, China which is valid till 29/04/2020.
Omeprazole: Firm has submitted copy GMP Certificate of manufacturer "M/s Metrochem API Pvt. Ltd, INDIA" issued by Drugs Control Administration, Government of Telangara, India valid till 2018.</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>• ASPIRIN API:
Photocopy of COA of Batch No. CA1709001 issued by "M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA" is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Aspirin), USP Reference Standard and impurity standards provided by the API Manufacturer - M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA.
• OMEPRAZOLE API:
Photocopy of COA of Batch No. OMP/1709477 issued by M/s Metrochem API Pvt. Ltd, INDIA is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Omeprazole),USP Reference Standard and impurity standards provided by the API Manufacturer - M/s Metrochem API Pvt. Ltd, INDIA along with procuring invoice of Reference standard & impurity standards.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of COAs 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</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 generalized SOP with the title 'Protocol For Development of New Product'.
Effective date 12-08-2017.</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="4">OMP TABLETS 81/40mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>TF001</td><td>500 Tabs</td><td>16-01-2018</td><td>16-01-2018</td></tr>
<tr><td>TF002</td><td>500 Tabs</td><td>17-01-2018</td><td>17-01-2018</td></tr>
<tr><td>TF003</td><td>500 Tabs</td><td>18-01-2018</td><td>18-01-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>OMO Tablets 81/40mg ;
Stability Pack Size : 3 x 10's
• TF001: Batch Size : 500 Tablets
Yield 492 Tablets (16 Packs) , 01 Pack used for testing</td></tr>
</table>

		method validation. 01 Pack used for Initial testing, 01 Pack used for Comparative Dissolution Profile. 13 (3x10's) Packs placed on stability (Accelerated : 03 Packs , Real Time : 10 Packs) out of which 09 packs are remaining (Accelerated : 01 Pack , Real Time : 08 Packs). • TF002: Batch Size : 500 Tablets Yield 493 Tablets (16 Packs) , 01 Pack used for Initial testing. 15 (3x10's) Packs placed on stability (Accelerated : 03 Packs , Real Time : 12 Packs) out of which 11 packs are remaining (Accelerated : 01 Pack , Real Time : 10 Packs). • TF003: Batch Size : 500 Tablets Yield 490 Tablets (16 Packs) , 01 Pack used for Initial testing. 15 (3x10's) Packs placed on stability (Accelerated : 03 Packs , Real Time : 12 Packs) out of which 11 packs are remaining (Accelerated: 01 Pack , Real Time : 10 Packs).
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:** The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability software V5.7T Thermo, India & for Accelerated Stability studies, software is Logit Chrt; Technoman; Pakistan) & the data can been verified for 01 year. Now 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 (Aspirin) & Omeprazole) 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 OMO Tablets 81/40mg & OMO Tablets 325/40mg. • 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.	**ASPIRIN:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) &**long term, 48 Months** (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of ASPIRIN from M/s JQC (Huayin) Pharmaceutical Co. Ltd. CHINA. **OMEPRAZOLE:** The firm has submitted copy of **accelerated, 06 Months** (25°C ± 2°C & 60±5%RH) &**long term, 60 Months** (5°C ± 3°C) stability study reports of 03 batches of Omeprazole from M/s Metrochem API Pvt. Ltd, INDIA.
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 (YOSPRALA).

<table>
<tr>
<td>18.</td>
<td>Record of comparative dissolution data.</td>
<td>

Firm has submitted Comparative dissolution study of their product (OMO Tablets all SKUs (81/40mg & 325/40mg) with Innovator's Brand "YOSPRALS" conducted on following dates ;
81/40 mg : 29/11/2018 to 04/12/2018
325/40mg: 06/12/2018 to 12/12/2018
The details are as follows:

<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of HELIX Pharma</th></tr>
<tr><td>Brand name</td><td>YOSPRALA Tablets 81mg/40mg</td><td>OMO Tablets 81/40mg</td></tr>
<tr><td>Batch No.</td><td>3146921</td><td>TF001</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned
Exp. 07-2019</td><td>01-2018</td></tr>
</table>
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of HELIX Pharma</th></tr>
<tr><td>Brand name</td><td>YOSPRALA Tablets 325mg/ 40mg</td><td>OMO Tablets 325/40mg</td></tr>
<tr><td>Batch No.</td><td>3149884</td><td>TF001</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned
Exp. 06-2019</td><td>01-2018</td></tr>
</table>

Comparative dissolution studies have been performed in following media:

<u>ASPIRIN</u> :
i. 0.1N Hydrochloric Acid Solution
ii. pH 4.5 Acetate buffer solution.
iii. pH 6.8 phosphate buffer solution.
<u>OMEPRAZOLE</u> :
i. 1.2N Hydrochloric Acid Solution
ii. pH 4.5 Acetate buffer solution.
iii. pH 6.8 phosphate buffer solution.

Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies.

</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 of OMO TABLETS 81/40mg & OMO TABLETS 325/40mg.</td>
</tr>
</table>

Evaluation by PEC:

Deficiency/Observation	**Response by Pharma.**
Clarification regarding GMP certificate, as on GMP name of firm is JQC (Huayian) Pharmaceuticals but on china FDA site firm certified under the provided certificate number is Huayin Jinjincheng Pharmaceutical Co., Ltd. Is mentioned	Firm replied that the submitted GMP for manufacturer of Aspirin JQC (Huayian) Pharmaceuticals is the abbreviation of Huayin Jinjincheng Pharmaceutical Co., Ltd. Is mentioned on SFDA.
The GMP certificate of Metrochem API Pvt Ltd, India is not valid after 2-2018. Provide the valid GMP certificate	The GMP certificate of Metrochem API Pvt Ltd, India valid up to 11-1-2019. Is provided
Mechanism for Vendor pre-qualification and list of R&D staff not attached only annexure heading is attached	Provided
API stability of omeprazole at conditions of zone IV-A as provided stability is at Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C.	The storage conditions of omeprazole is at cold conditions that's whyAPI stability of omeprazole was provided at Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C.

The innovators finished product release specifications tests for this dosage form including tests for content uniformity Justify the exemption of these tests as it is very important becauseomeprazole is being incorporated via coating solution.	As per USP monographs of uniformity of contents if the weight of the API is more than 25 mg then the content uniformity test is optional however as per your requirement they provides the content uniformity test of omeprazole on the base of weight variation
Since API of omeprazole is being incorporated via coating solution so how it is possible to ensure that proper amount of active has been incorporated in dosage form while using 100% quantity in master formulation	Since API of omeprazole is being incorporated via coating solution to ensure proper amount of active has been incorporated in dosage using 50% overage that has already been submitted along with stability.

Decision: Registration board decided to defer the case for submission of stability studies of three batches of API both accelerated & real time according to 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 GMP Inspection Report Date & Remarks
1003.	**M/s Helix Pharma (Pvt.) Ltd. A-56, SITE, Manghopir road, Karachi.**	OMO / ASPER TABLETS 325 mg/40mg Each tablet contains: Aspirin (Delayed-release)….325 mg Omeprazole (Immediate release) .....40 mg (PPI and analgesic) Firm has claimed Mfg. Specs. (Helix Pharma)	Form-5D Dy. No. 1575 04-5-2017 Rs. 50,000/- (Challan # 0587027) Pack Size: 10's , 20's & 30's (As per PRC)	YOSPRALA Tablets 325mg/40mg by Arelez Pharmaceuticals US Inc. Not applicable GMP compliant dated 24/9/2018

STABILITY STUDY DATA			
Drug	OMO / ASPER TABLETS 325 mg/40mg (Aspirin + Omeprazole)		
Name of Manufacturer	Helix Pharma (Pvt.) Ltd., Karachi.		
Manufacturer of API	Aspirin: M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA.		
	Omeprazole: M/s Metrochem API Pvt. Ltd, INDIA.		
API Lot No.	Aspirin : CA1709001 Omeprazole : OMP/1709477		
Description of Pack (Container closure system)	Alu / Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time : 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, 3 ,6 (Months) Real Time : 0, 3 ,6 (Months)		
Batch No.	TF 001	TF 002	TF 003
Batch Size	500 Tablets	500 Tablets	500 Tablets

Manufacturing Date	01 - 2018	01 – 2018	01 – 2018
Date of Initiation	02-02-2018	02-02-2018	02-02-2018
No. of Batches	TF 001		
Date of Submission	4211 (3/1/2019)		

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.	**Aspirin:** Firm has submitted copy of GMP Certificate of manufacturer "JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA." issued by SFDA,China which is valid till 29/04/2020. **Omeprazole:** Firm has submitted copy GMP Certificate of manufacturer "M/s Metrochem API Pvt. Ltd, INDIA" issued by Drugs Control Administration, Government of Telangara, 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 (Karachi) attested invoice 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

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter No. 1857 (R&I) dated 15-01-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 276th Meeting.

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 RAMELTON Tablets 8mg (Ramelteon) in its 273rd Meeting. o Date of Inspection: 18-08-2017. o The HPLC is 21CFR Compliant. o Audit trail on the testing reports of ―Ramelton (Ramelteon) Tablets 8mg were available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 30-11-2017, Commercial Invoice attestation on dated 30/11/2017 for 0.8 Kg of Aspirin **Omeprazole:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 24-10-2017, Commercial Invoice attestation on dated 24/10/2017 for 2.0 Kg of Omeprazole .

<table>
<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.
• The firm has clarified 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>Aspirin: Firm has submitted copy of GMP Certificate of manufacturer "JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA." issued by SFDA,China which is valid till 29/04/2020.

Omeprazole: Firm has submitted copy GMP Certificate of manufacturer "M/s Metrochem API Pvt. Ltd, INDIA" issued by Drugs Control Administration, Government of Telangara , India.</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>• ASPIRIN API:
Photocopy of COA of Batch No. CA1709001 issued by "M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA" is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Aspirin), USP Reference Standard and impurity standards provided by the API Manufacturer - M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA.
• OMEPRAZOLE API:
Photocopy of COA of Batch No. OMP/1709477 issued by M/s Metrochem API Pvt. Ltd, INDIA is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Omeprazole),USP Reference Standard and impurity standards provided by the API Manufacturer - M/s Metrochem API Pvt. Ltd, INDIA along with procuring invoice of Reference standard & impurity standards.</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 copy of generalized SOP with the title 'Protocol For Development Of New Product'.
Effective date 12-08-2017.</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="4">OMP TABLETS 325/40mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>TF001</td><td>500 Tabs</td><td>22-01-2018</td><td>22-01-2018</td></tr>
<tr><td>TF002</td><td>500 Tabs</td><td>23-01-2018</td><td>23-01-2018</td></tr>
<tr><td>TF003</td><td>500 Tabs</td><td>24-01-2018</td><td>24-01-2018</td></tr>
</table>
</td></tr>
</table>

11.	Record of remaining quantities of stability batches.	**OMO Tablets 325/40mg ;** **Stability Pack Size : 3 x 10's** • TF001: Batch Size : 500 Tablets Yield 492 Tablets (16 Packs) , 01 Pack used for testing method validation. 01 Pack used for Initial testing, 01 Pack used for Comparative Dissolution Profile. 13 (3x10's) Packs placed on stability (Accelerated : 03 Packs , Real Time : 10 Packs) out of which 09 packs are remaining (Accelerated : 01 Pack , Real Time : 08 Packs). • TF002: Batch Size : 500 Tablets Yield 493 Tablets (16 Packs) , 01 Pack used for Initial testing. 15 (3x10's) Packs placed on stability (Accelerated : 03 Packs , Real Time : 12 Packs) out of which 11 packs are remaining (Accelerated : 01 Pack , Real Time : 10 Packs). • TF002: Batch Size : 500 Tablets Yield 493 Tablets (16 Packs) , 01 Pack used for Initial testing. 15 (3x10's) Packs placed on stability (Accelerated : 03 Packs , Real Time : 12 Packs) out of which 11 packs are remaining (Accelerated : 01 Pack , Real Time : 10 Packs).
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:** The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability software V5.7T Thermo, India & for Accelerated Stability studies, software is Logit Chrt; Technoman; Pakistan) & the data can been verified for 01 year. Now 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 (Aspirin) & Omeprazole) 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 OMO Tablets 81/40mg & OMO Tablets 325/40mg. • 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.	**ASPIRIN :** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5%RH) &**long term, 48 Months** (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of ASPIRIN from M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA. **OMEPRAZOLE:** The firm has submitted copy of **accelerated, 06 Months** (25°C ± 2°C & 60±5%RH) &**long term, 60 Months** (5°C ± 3°C) stability study reports of 03 batches of Omeprazole from M/s Metrochem API Pvt. Ltd, INDIA.
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 (YOSPRALA).

<table>
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<td>18.</td>
<td>Record of comparative dissolution data.</td>
<td>

Firm has submitted Comparative dissolution study of their product (OMO Tablets all SKUs (81/40mg & 325/40mg) with Innovator's Brand "YOSPRALS" conducted on following dates ;
81/40 mg : 29/11/2018 to 04/12/2018
325/40mg : 06/12/2018 to 12/12/2018
The details are as follows:

<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of HELIX Pharma</th></tr>
<tr><td>Brand name</td><td>YOSPRALA Tablets 81mg/40mg</td><td>OMO Tablets 81/40mg</td></tr>
<tr><td>Batch No.</td><td>3146921</td><td>TF001</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned
Exp. 07-2019</td><td>01-2018</td></tr>
</table>
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of HELIX Pharma</th></tr>
<tr><td>Brand name</td><td>YOSPRALA Tablets 325mg/40mg</td><td>OMO Tablets 325/40mg</td></tr>
<tr><td>Batch No.</td><td>3149884</td><td>TF001</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned
Exp. 06-2019</td><td>01-2018</td></tr>
</table>

Comparative dissolution studies have been performed in following media:

<u>ASPIRIN :</u>
i. 0.1N Hydrochloric Acid Solution
ii. pH 4.5 Acetate buffer solution.
iii. pH 6.8 phosphate buffer solution.
<u>OMEPRAZOLE :</u>
i. 1.2N Hydrochloric Acid Solution
ii. pH 4.5 Acetate buffer solution.
iii. pH 6.8 phosphate buffer solution.

Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies.

</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 of OMO TABLETS 81/40mg & OMO TABLETS 325/40mg.</td>
</tr>
</table>

Evaluation by PEC:

Deficiency/Observation	**Response by Pharma.**
Clarification regarding GMP certificate, as on GMP name of firm is JQC (Huayian) Pharmaceuticals but on china FDA site firm certified under the provided certificate number is Huayin Jinjincheng Pharmaceutical Co., Ltd. Is mentioned	Firm replied that the submitted GMP for manufacturer of Aspirin JQC (Huayian) Pharmaceuticals is the abbreviation of Huayin Jinjincheng Pharmaceutical Co., Ltd. Is mentioned on SFDA.
The GMP certificate of Metrochem API Pvt Ltd, India is not valid after 2-2018. Provide the valid GMP certificate	The GMP certificate of Metrochem API Pvt Ltd, India valid up to 11-1-2019. Is provided
Mechanism for Vendor pre-qualification and list of R&D staff not attached only annexure heading is attached	Provided
API stability of omeprazole at conditions of zone IV-A as provided stability is at Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C.	The storage conditions of omeprazole is at cold conditions that's whyAPI stability of omeprazole was provided at Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C.

The innovators finished product release specifications tests for this dosage form including tests for content uniformity Justify the exemption of these tests as it is very important becauseomeprazole is being incorporated via coating solution.	As per USP monographs of uniformity of contents if the weight of the API is more than 25 mg then the content uniformity test is optional however as per your requirement they provides the content uniformity test of omeprazole on the base of weight variation
Since API of omeprazole is being incorporated via coating solution so how it is possible to ensure that proper amount of active has been incorporated in dosage form while using 100% quantity in master formulation	Since API of omeprazole is being incorporated via coating solution to ensure proper amount of active has been incorporated in dosage using 50% overage that has already been submitted along with stability.

Decision: Registration Board decided to approve registration of "OMO / ASPER TABLETS 325 mg/40mg (Aspirin + Omeprazole) by M/ s Helix Pharma (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 GMP Inspection Report Date & Remarks
1004.	M/s Helix Pharma (Pvt.) Ltd. A-56, S.I.T.E, Manghopir road, Karachi.	NAP-X Tablets 500/20mg Each tablet contains: Naproxen (delayed released) ……..500mg Esomeprazole as magnesium (immediate release)……20mg Firm has claimed Mfg. Specs. (Helix Pharma)	Form-5D Dy. No. Duplicate dossier 08-2010 Rs. 150,00/-(27-Aug-2010), 90,000/-(31-5-2013 Challan # 0001138) Duplicate Pack Size: 10's , 20's , 30's (As per PRC)	VIMOVO Tablets 500/20mg by AstraZeneca Canada Inc. Not applicable GMP compliant dated 24/09/2018

STABILITY STUDY DATA

Drug	NAP-X Tablets 500/20mg (Naproxen + Esomeprazole)		
Name of Manufacturer	Helix Pharma (Pvt.) Ltd., Karachi.		
Manufacturer of API	**Naproxen Sodium:** M/s Zhejiang Charioteer Pharmaceutical Co., Ltd. CHINA.		
	Esomeprazole -Mg: M/s Smilax Laboratories Ltd, Plot # 70 & 71, JN Pharma city, Parawada, Visakhapatnam-531021, Andhera Pradesh INDIA.		
API Lot No.	**Naproxen Sodium:** 176315A61 **Esomeprazole -Mg:** EOV1705007		
Description of Pack (Container closure system)	Alu / Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time : 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, 3 ,6 (Months) Real Time : 0, 3 ,6 (Months)		
Batch No.	TF 001	TF 002	TF 003
Batch Size	1000 Tablets	1000 Tablets	1000 Tablets

Manufacturing Date	02 – 2018	02 - 2018	02 – 2018
Date of Initiation	16-02-2018	16-02-2018	16-02-2018
No. of Batches	03		
Date of Submission	8552 (26/2/19)		

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.	**Naorpxen Sodium:** Firm has submitted copy of GMP Certificate of manufacturer "Zhejiang Charioteer Pharmaceutical Co., Ltd. CHINA." (# ZJ20150090) issued by SFDA, China which is valid till 07/06/2020. **Esomeprazole-Mg:** Firm has submitted copy GMP Certificate of manufacturer "M/s Smilax Laboratories Ltd, INDIA" (#1550/DD/ DCA/VSP/2017) issued by Drugs Control Administration, Visakhapatnam Region, 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 (Karachi) attested invoice 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

- Dissolution is according to USFDA.

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter No. 1857 (R&I) dated 15-01-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 276th Meeting.

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 RAMELTON Tablets 8mg (Ramelteon) in its 273rd Meeting. o Date of Inspection: 18-08-2017. o The HPLC is 21CFR Compliant. o Audit trail on the testing reports of ―Ramelton (Ramelteon) Tablets 8mg were available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Naproxen Sodium:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 07-02-2018, Commercial Invoice attestation on dated 07/02/2018 for 2.5 Kg of Naproxen Sodium. **Esomeprazole-Mg:** The firm has submitted photocopies of FedEx paper along with Proforma Invoice for Esomeprazole-Mg.

<table>
<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.
• The firm has clarified 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>Naorpxen Sodium: Firm has submitted copy of GMP Certificate of manufacturer "Zhejiang Charioteer Pharmaceutical Co., Ltd. CHINA." issued by SFDA, China which is valid till 07/06/2020.
Esomeprazole-Mg: Firm has submitted copy GMP Certificate of manufacturer "M/s Smilax Laboratories Ltd, INDIA" issued by Drugs Control Administration, Visakhapatnam Region, India. Valid up to 1-2019</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 API's manufacturer.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Naproxen Sodium API:
Photocopy of COA of Batch No. 176315A61 issued by "Zhejiang Charioteer Pharmaceutical Co.,Ltd. CHINA" is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Naproxen Sodium), USP Reference Standard.
Esomeprazole - Mg API:
Photocopy of COA of Batch No. EOV1705007 issued by M/s Smilax Laboratories Ltd, INDIA is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Esomeprazole-Mg),USP Reference Standard.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of COAs/Procurement documents 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</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 generalized SOP with the title 'Protocol For Development Of New Product'.
Effective date 12-08-2017.</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="4">NAP-X TABLETS 500/20mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>TF001</td><td>1000 Tabs</td><td>02-02-2018</td><td>03-02-2018</td></tr>
<tr><td>TF002</td><td>1000 Tabs</td><td>06-02-2018</td><td>07-02-2018</td></tr>
<tr><td>TF003</td><td>1000 Tabs</td><td>08-02-2018</td><td>09-02-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>NAP-X Tablets 500/20mg ;
Stability Pack Size : 30's
• TF001: Batch Size : 1000 Tablets
Yield 985 Tablets (32 Packs) , 02 Pack used for testing method validation. 01 Pack used for Initial testing, 02 Pack used for Comparative Dissolution Profile. 15 (3x10's) Packs placed on stability (Accelerated : 06 Packs , Real Time : 9 Packs) out of which 11 packs are remaining (Accelerated : 04 Pack , Real Time : 07 Packs).</td></tr>
</table>

<table>
<tr><td></td><td></td><td>• TF002: Batch Size : 1000 Tablets
Yield 987 Tablets (32 Packs) , 01 Pack used for Initial testing. 15 (3x10's) Packs placed on stability (Accelerated : 06 Packs , Real Time : 09 Packs) out of which 11 packs are remaining (Accelerated : 04 Pack , Real Time : 07 Packs).
• TF003: Batch Size : 1000 Tablets
Yield 989 Tablets (32 Packs) , 01 Pack used for Initial testing. 15 (3x10's) Packs placed on stability (Accelerated : 06 Packs , Real Time : 09 Packs) out of which 11 packs are remaining (Accelerated : 04 Pack , Real Time : 07 Packs).</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>• Previously Reported in panel inspection:
The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability software V5.7T Thermo, India & for Accelerated Stability studies, software is Logit Chrt; Technoman; Pakistan) & the data can been verified for 01 year.
Now, the firm has submitted copy of record of digital data logger (Logit Chart, Technoman) 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 (Naproxen Sodium) & Esomeprazole-Mg) 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 NAP-X Tablets 500/20mg.
• 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>NAPROXEN SODIUM : The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) &long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Naproxen Sodium from M/s Zhejiang Charioteer Pharmaceutical Co.,Ltd. CHINA.
ESOMEPRAZOLE : The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) &long term, 36 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Esomeprazole from M/s Smilax Laboratories Ltd, INDIA.</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 (VIMOVO).</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative dissolution study of their product (NAP-X Tablets 500/20mg with Innovator's Brand "VIMOVO" conducted on following dates ;
• 500/20 mg : 09/01/2019 to 15/01/2019
• The details are as follows:
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Helix Pharma</th></tr>
<tr><td>Brand name</td><td>VIMOVO Tablets 500mg/20mg</td><td>NAP-X Tablets 500/ 20mg</td></tr>
<tr><td>Batch No.</td><td>DAGN</td><td>TF 001</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned
Exp.</td><td>02-2018</td></tr>
</table>
• Comparative dissolution studies have been performed in following media:</td></tr>
</table>

		NAPROXEN : i. 0.1N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 Phosphate buffer solution. **ESOMEPRAZOLE :** i. 1.2N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 7.4 phosphate buffer solution. • 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 of NAP-X TABLETS 500/20mg.

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.	The innovator product is as naproxen alone not as naproxen sodium as applied by the firm. Justification is needed	Please be informed that "we have applied formulation naproxen + esomeprazole a magnesium in applied dossier. In submitted stability data we are using salt of naproxen i.e. naproxen sodium but we have derived contents naproxen by applying factor in the calculation sheets".
i.	The GMP certificate of Smilax lab Ltd, India is not valid after 1-2019. Provide the valid GMP certificate	GMP certificate of Smilax lab Ltd, India issued on 18-1-2019 valid for 3 years is provided.
i.	Documents for the procurement of API esomeprazole with approval from DRAP is needed as only the photocopies of FedEx invoice is submitted without any AD attestation	Firm reply that they received the documents through FedEx. FedEx documents are provided
i.	In USFDA dissolution method, Type II (Paddle) with sinkers are used but in applied finished product specification sinker I not mentioned. Clarification is needed	The firm claim that "we have followed USFDA dissolution method by using type II (Peddle) and sinkers but missed to mentioned sinkers in FP testing method and comparative dissolution profile. We are enclosing revised FP testing protocol along with procuring documents od sinkers"
i.	API stability of esomeprazole at Accelerated conditions is not submitted	Provided

Decision:Registration Board decided to reject the registration application of applied formulation as it contains Naproxen Sodium but reference product product contains Naproxen only so the applied formulation is not generic to innovator.

1005.	Duplicate Of Case At Serial No. 990

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1006.	M/s Wilsons's Pharmaceuticals Plot No. 387-388, Sector I-9 Industrial area, Islamabad.	Sofvasc Trio Tablet Each film coated Tablet contains: Olmesartan medoxomil ….40mg Amlodipine as besylate …….10mg Hydrochlorothiazide ……...25 mg Anti-Hypertensive agent Diuretic	Form-5-D Fast Track 10's, 20's & 30's Rs.559/- per tablet 11-12-2010/ 335 17-05-2013/ 3125 Rs.60,000/- (duplicate)	Tribenzor, USFDA approved Triday of werrick pharma GMP compliant dated 24-01-2018 "Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."

STABILITY STUDY DATA			
Drug	Sofvasc Trio Tablet		
Name of Manufacturer	M/s Wilsons's Pharmaceuticals Plot No. 387-388, Sector I-9 Industrial area, Islamabad.		
Manufacturer of API	**Amlodipine besilate**: M/s Hetero Drugs Limited (Unit-IV), India.		
	Olmesartan medoxomil: M/s Glenmark Pharmaceuticals Ltd. India.		
	Hydrochlorothiazide: M/s Suzhou Lixin Pharmaceutical Co. Ltd, China		
API Lot No.	**Olmesartan medoxomil:** 83170554 **Amlodipine besilate:** AM0321216 and AM0331216 **Hydrochlorothiazide:** C01-20170102		
Description of Pack (Container closure system)	Alu / Alu Blister Pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH 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) Real Time : 0, 3 ,6 (Months)		
Batch No.	Trail 001	Trail 001	Trail 001
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	26-2-2018	26-2-2018	26-2-2018
No. of Batches	03		
Date of Submission	14-1-2019 (D # 1670)		

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	**Olmesartan medoxomil:** M/s Glenmark Pharmaceuticals Ltd. India:

	issued by regulatory authority of country of origin.	Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. **Amlodipine besilate:** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 21-04-2018 is submitted. **Hydrochlorothiazide:** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. JS20140325 issued by Jiangsu Food and Drug Administration China, valid up to 25-08-2019 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.	Copy of ADC attested Form 5, form 3 and commercial invoice provided for all 3 actives. Amlodipine as besylate Quantity… 300 kg Olmesartan medoxomil Quantity… 100 kg Hydrochlorothiazide Quantity…300 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

. Above observation were communicated to firm vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-VII), to which firm has responded as under:

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 decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad in its 278th Meeting. Date of Inspection: 10-12-2015, 19-04-2017 & 20-01-2018 compliant and audit trail on the testing reports was available and confirmed.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine as besylate:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5, Commercial Invoice issued by M/s Hetero corporate, INDIA attestation on dated 23/Dec/2016 for 300 kg of Amlodipine. The firm has imported Raw Material ,Qty ; 12x25 kg ; Batch # AM0321216 and AM0331216 **Olmesartan medoxomil:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and commercial invoice dated

		11/10/2017. Commercial Invoice is issued by M/s Glenmark Pharma Ltd, INDIA Moreover detail of Qty; 10 kg; Batch 83170554 is mentioned on invoice. **Hydrochlorothiazide:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and AD attested commercial invoice issued by M/s Suzhou Lixin Pharmaceutical Co. Ltd, China dated 29/3/17. Commercial Invoice is issued by M/s Suzhou Lixin Pharma Co. Ltd, China Moreover detail of Qty; 300 kg ; Batch # C01-20170102 is mentioned on invoice
3.	Documents for the procurement of reference standard and impurity standards.	Hydrochlorthiazide Working Standard 1g from 3J Diagnostic, TRC Canada Impurities Impurity A (Suzhou Lixin Pharmaceutical Co. Ltd) Impurity B (Suzhou Lixin Pharmaceutical Co. Ltd) Chlorthiazide Benzothiadiazine Related Compound A Amlodipine Besylate Working Standard Working Standard 25g from 3J Diagnostic, , TRC Canada Olmesartan Medoxomil Working Standard Working Standard 1g from 3J Diagnostic, , TRC Canada Olmesartan Impurity A (Synpure Labs) Olmesartan Olefenic Impurity (Synpure Labs) Olmesartan Related Compound A(Synpure Labs) Omlesartan Alkyl Impurity(Synpure Labs)
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Amlodipine as besylate:** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 18-5-2020 is submitted. **Olmesartan medoxomil:** M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. **Hydrochlorothiazide:** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. JS20140325 issued by Jiangsu Food and Drug Administration China, valid up to 25-08-2019 is submitted.
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	**Amlodipine as besylate API:** Photocopy of COA of Batch No. AM0331216 issued by " M/s Hetero Drugs Limited (Unit-IV), India" is submitted. • **Reference standards and impurity standards:** The firm has submitted copy of Reference Standard and impurity standards are provided **Olmesartan medoxomil API:** Photocopy of COA of Batch No. 83170554 issued by M/s Glenmark Pharmaceuticals Ltd. India is submitted. • **Reference standards and impurity standards:** The firm has submitted copy of Reference Standard and impurity

<table>
<tr><td></td><td></td><td>standards are provided
Hydrochlorothiazide API:
Photocopy of COA of Batch No. C01-20170102 issued by M/s Suzhou Lixin Pharmaceutical Co. Ltd, China is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Reference Standard and impurity standards are provided</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. 17 personals 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 ‘Protocols/standard operating procedure for the development of Sofvasc trio tablet 40/10/25 mg tablet”
Effective date not mentioned</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>2-2018</td></tr>
<tr><td>Trail#2</td><td>1500 Tabs</td><td>2-2018</td></tr>
<tr><td>Trail#3</td><td>1500 Tabs</td><td>2-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Trapeze plus XR ;
Stability Pack Size :
• Trail #1: Batch Size : 1500 Tablets
Yield 1320 Tablets ,
124 tablets used for testing
other are remaining
• Trail #2: Batch Size : 1500 Tablets
Yield 1300 Tablets ,
124 tablets used for testing
other are remaining
• Trail #3: Batch Size : 1500 Tablets
Yield 1310 Tablets ,
124 tablets used for testing
other are remaining</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>• Previously Reported in panel inspection:
The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)
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.
• 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>
</table>

15.	Reports of stability studies of API from manufacturer.	**Amlodipine as besylate:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 36 Months** (30°C±2°C & 65±5% RH) stability study reports of 03 batches **Olmesartan medoxomil** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 48 Months** (30°C±2°C & 65±5%RH) stability study reports of 03 batches **Hydrochlorothiazide:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 48 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 Sofvasc trio with Innovator's Brand "Tribenzor" conducted on following dates: • Comparative dissolution studies have been performed in following media: **Olmesartan medoxomil:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **Amlodipine as besylate:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **Hydrochlorothiazide:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. • 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:

Dissolution parameters stated in finished product testing method, submitted along with stability studies data are recommended by USFDA.

Amlodipine Besylate/Hydrochlorothiazide/Olmesartan Medoxomil:

Tablet II (Paddle) 50 Phosphate Buffer, pH 6.8 900 5, 10, 15, 20, 30 and 45

Deficiency/Observation	**Response by Pharma.**
Submit raw data sheets of all time points. Provide concentrations of standard and sample solution used in assay and dissolution, as it is not clear from the provided method.	Provided

Clarification regarding peak resolution as some peaks are merged in method validation (e.g. in sample ID "sys suitably 6" and in "linearity-150%" etc.)	Peak resolution was found by the firm and new chromatograms are submitted. A resolution of 1.5 or greater between the peaks will ensure that the sample components are well (baseline) separated to degree at which the area or height of each peak may be accurately measured. No resolution was found to be less than 2.
Valid GMP certificate is required as Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India was valid up to 21-04-2018	Valid GMP certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India was valid up to 21-04-2018 is provided
List of qualified staff involved in product development with relevant experience does not mentioned their qualifications.	Provided
COA of Impurity standard of amlodipine are not provided same is required.	Provided
Impurities analysis not performed for finished product. Clarify and justify	Provided

Decision: Registration Board decided to approve registration of "Sofvasc Trio Tablet 40/10/25 mg by Wilsons's Pharmaceuticals, Islamabad. 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 GMP Inspection Report Date & Remarks
1007.	M/s Wilsons's Pharmaceuticals Plot No. 387-388, Sector I-9 Industrial area, Islamabad.	Sofvasc Trio Tablet 40/5/25 mg Each film coated Tablet contains: Olmesartan medoxomil ….40 mg Amlodipine as besylate …….5 mg Hydrochlorothiazide ……...25 mg Anti-Hypertensive agent Diuretic	Form-5-D Fast Track 10's,20's&30' s Rs.522/- per tablet 11-12-2010/337 17-05-2013/ 3125 Rs.60,000/- (duplicate)	Tribenzor, USFDA approved Triday of werrick pharma GMP compliant dated 24-01-2018 "Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection"

STABILITY STUDY DATA	
Drug	Sofvasc Trio Tablet 40/5/25 mg
Name of Manufacturer	M/s Wilsons's Pharmaceuticals Plot No. 387-388, Sector I-9 Industrial area, Islamabad.
Manufacturer of API	**Amlodipine besilate**: M/s Hetero Drugs Limited (Unit-IV), India.
	Olmesartan medoxomil: M/s Glenmark Pharmaceuticals Ltd. India.
	Hydrochlorothiazide: M/s Suzhou Lixin Pharmaceutical Co. Ltd, China
API Lot No.	**Olmesartan medoxomil:** 83170554 **Amlodipine besilate:** AM0321216 and AM0331216 **Hydrochlorothiazide:** C01-20170102
Description of Pack (Container closure system)	Alu / Alu Blister Pack

Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH 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) Real Time : 0, 3 ,6 (Months)		
Batch No.	Trail 001	Trail 001	Trail 001
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	18-2-2018	18-2-2018	18-2-2018
No. of Batches	03		
Date of Submission	14-1-2019 (D # 1669)		

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.	**Olmesartan medoxomil:** M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. **Amlodipine besilate:** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 21-04-2018 is submitted. **Hydrochlorothiazide:** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. JS20140325 issued by Jiangsu Food and Drug Administration China, valid up to 25-08-2019 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.	Copy of ADC attested Form 5, form 3 and commercial invoice provided for all 3 actives. Amlodipine as besylate Quantity… 300 kg Olmesartan medoxomil Quantity… 100 kg Hydrochlorothiazide Quantity…300 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,	Yes

	1978.	
REMARKS OF EVALUATOR		
. Above observation were communicated to firm vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-VII), to which firm has responded as under:		
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 decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad in its 278th Meeting. Date of Inspection: 10-12-2015, 19-04-2017 & 20-01-2018 compliant and audit trail on the testing reports was available and confirmed.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine as besylate:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5, Commercial Invoice issued by M/s Hetero corporate, INDIA attestation on dated 23/Dec/2016 for 300 kg of Amlodipine. The firm has imported Raw Material ,Qty ; 12x25 kg ; Batch # AM0321216 and AM0331216 **Olmesartan medoxomil:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and commercial invoice dated 11/10/2017. Commercial Invoice is issued by M/s Glenmark Pharma Ltd, INDIA Moreover detail of Qty; 10 kg; Batch 83170554 is mentioned on invoice. **Hydrochlorothiazide:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and AD attested commercial invoice issued by M/s Suzhou Lixin Pharmaceutical Co. Ltd, China dated 29/3/17. Commercial Invoice is issued by M/s Suzhou Lixin Pharma Co. Ltd, China Moreover detail of Qty; 300 kg ; Batch # C01-20170102 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 and impurity standard purchased from different source other then API manufacturer.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Amlodipine as besylate:** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 18-5-2020 is submitted. **Olmesartan medoxomil:** M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. **Hydrochlorothiazide:** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. SU20160171 issued by Jiangsu Food and Drug Administration China, valid up to 31-december-2020 is submitted.
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	**Amlodipine as besylate API:**

<table>
<tr><td></td><td>API, reference standards and impurity standards</td><td>Photocopy of COA of Batch No. AM0331216 issued by " M/s Hetero Drugs Limited (Unit-IV), India" is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Reference Standard and impurity standards are provided
Olmesartan medoxomil API:
Photocopy of COA of Batch No. 83170554 issued by M/s Glenmark Pharmaceuticals Ltd. India is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Reference Standard and impurity standards are provided
Hydrochlorothiazide API:
Photocopy of COA of Batch No. C01-20170102 issued by M/s Suzhou Lixin Pharmaceutical Co. Ltd, China is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Reference Standard and impurity standards are provided</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. 17 personals 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 'Protocols/standard operating procedure for the development of Sofvasc trio tablet 40/10/25 mg tablet"
Effective date not mentioned</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>2-2018</td></tr><tr><td>Trail#2</td><td>1500 Tabs</td><td>2-2018</td></tr><tr><td>Trail#3</td><td>1500 Tabs</td><td>2-2018</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Trapeze plus XR ;
Stability Pack Size :
• Trail #1: Batch Size : 1500 Tablets
600 tablets used for stability
568 are remaining
• Trail #2: Batch Size : 1500 Tablets
600 tablets used for stability
568 are remaining
• Trail #3: Batch Size : 1500 Tablets
600 tablets used for stability
568 are remaining</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>• Previously Reported in panel inspection:
The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)
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>
</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 Specifications and Testing Method of applied product and its validation data. • 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.	**Amlodipine as besylate:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 36 Months** (30°C±2°C & 65±5% RH) stability study reports of 03 batches **Olmesartan medoxomil** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 48 Months** (30°C±2°C & 65±5%RH) stability study reports of 03 batches **Hydrochlorothiazide:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 48 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 Sofvasc trio with Innovator's Brand "Tribenzor" conducted on following dates ; • Comparative dissolution studies have been performed in following media: **Olmesartan medoxomil:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **Amlodipine as besylate:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **Hydrochlorothiazide:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. • 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:

Dissolution parameters stated in finished product testing method, submitted along with stability studies data are recommended by USFDA.

Amlodipine Besylate/Hydrochlorothiazide/Olmesartan Medoxomil:

Tablet II (Paddle) 50 Phosphate Buffer, pH 6.8 900 5, 10, 15, 20, 30 and 45

Deficiency/Observation	**Response by Pharma.**
Qualification of qualified person not mentioned	------
COA of Impurity standard are not provided and some COA's of standards were purchased from different manufacture (TRC, Synpure labs, then the API manufacturer. Justify/clarify.	
COA of Impurity standard of amlodipine are not provided same is required.	-------

Decision: Registration Board after thorough deliberation deferred the case for scientific justification of use of working standard from manufacturer other than API manufacturer.

Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability GMP Inspection Report Date &Remarks**
1008.	M/s Wilsons's Pharmaceuticals Plot No. 387-388, Sector I-9 Industrial area, Islamabad.	Sofvasc Trio Tablet Each Tablet contains: Olmesartan medoxomil ….20mg Amlodipine as besylate …..5mg Hydrochlorothiazide ……..12.5mg Anti-Hypertensive agent Diuretic	Form-5-D Fast Track 10's, 20's & 30's Rs.410/- per tablet 11-12-2010/339 17-05-2013/ 3125 Rs.60,000/- (duplicate)	Tribenzor, USFDA approved Triday of werrick pharma GMP compliant dated 24-01-2018 "Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection"

STABILITY STUDY DATA

Drug	Sofvasc Trio Tablet 20/5/12.5 mg
Name of Manufacturer	M/s Wilsons's Pharmaceuticals Plot No. 387-388, Sector I-9 Industrial area, Islamabad.
Manufacturer of API	**Amlodipine besilate**: M/s Hetero Drugs Limited (Unit-IV), India.
	Olmesartan medoxomil: M/s Glenmark Pharmaceuticals Ltd. India.
	Hydrochlorothiazide: M/s Suzhou Lixin Pharmaceutical Co. Ltd, China
API Lot No.	**Olmesartan medoxomil:** 83170554 **Amlodipine besilate:** AM0321216 and AM0331216 **Hydrochlorothiazide:** C01-20170102
Description of Pack (Container closure system)	Alu / Alu Blister Pack
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH 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) Real Time : 0, 3 ,6 (Months)		
Batch No.	Trail 001	Trail 001	Trail 001
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	10-2-2018	10-2-2018	10-2-2018
No. of Batches	03		
Date of Submission	29-4-2018 (D # 39269)		

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.	**Olmesartan medoxomil:** M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. **Amlodipine besilate:** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 21-04-2018 is submitted. **Hydrochlorothiazide:** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. JS20140325 issued by Jiangsu Food and Drug Administration China, valid up to 25-08-2019 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.	Copy of ADC attested Form 5, form 3 and commercial invoice provided for all 3 actives. Amlodipine as besylate Quantity… 300 kg Olmesartan medoxomil Quantity… 100 kg Hydrochlorothiazide Quantity…300 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		
Above observation were communicated to firm vide letter no. F.1-1/2017/PEC-DRAP (AD PEC-VII), to which firm has responded as under:		
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 decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad in its 278th Meeting. Date of Inspection: 10-12-2015, 19-04-2017 & 20-01-2018 compliant and audit trail on the testing reports was available and confirmed.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Amlodipine as besylate:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5, Commercial Invoice issued by M/s Hetero corporate, INDIA attestation on dated 23/Dec/2016 for 300 kg of Amlodipine. The firm has imported Raw Material ,Qty ; 12x25 kg ; Batch # AM0321216 and AM0331216 **Olmesartan medoxomil:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and commercial invoice dated 11/10/2017. Commercial Invoice is issued by M/s Glenmark Pharma Ltd, INDIA Moreover detail of Qty; 10 kg; Batch 83170554 is mentioned on invoice. **Hydrochlorothiazide:** The firm has submitted photocopies of ADC (Islamabad) attested Form 5 and AD attested commercial invoice issued by M/s Suzhou Lixin Pharmaceutical Co. Ltd, China dated 29/3/17. Commercial Invoice is issued by M/s Suzhou Lixin Pharma Co. Ltd, China Moreover detail of Qty; 300 kg ; Batch # C01-20170102 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 and impurity standard purchased from different source other then API manufacturer.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Amlodipine as besylate:** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 18-5-2020 is submitted. **Olmesartan medoxomil:** M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. **Hydrochlorothiazide:** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. SU20160171 issued by Jiangsu Food and Drug Administration China, valid up to 31-december-2020 is submitted.
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	**Amlodipine as besylate API:** Photocopy of COA of Batch No. AM0331216 issued by " M/s Hetero Drugs Limited (Unit-IV), India" is submitted. • **Reference standards and impurity standards:**

<table>
<tr><td></td><td></td><td>The firm has submitted copy of Reference Standard and impurity standards are provided
Olmesartan medoxomil API:
Photocopy of COA of Batch No. 83170554 issued by M/s Glenmark Pharmaceuticals Ltd. India is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Reference Standard and impurity standards are provided
Hydrochlorothiazide API:
Photocopy of COA of Batch No. C01-20170102 issued by M/s Suzhou Lixin Pharmaceutical Co. Ltd, China is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Reference Standard and impurity standards are provided</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. 16 personals 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 ‘Protocols/standard operating procedure for the development of Sofvasc trio tablet 20/5/12.5mg tablet”</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>2-2018</td></tr>
<tr><td>Trail#2</td><td>1500 Tabs</td><td>2-2018</td></tr>
<tr><td>Trail#3</td><td>1500 Tabs</td><td>2-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Trapeze plus XR ;
Stability Pack Size:
• Trail #1: Batch Size : 1500 Tablets
600 tablets used for stability
568 are remaining
• Trail #2: Batch Size : 1500 Tablets
600 tablets used for stability
568 are remaining
• Trail #3: Batch Size : 1500 Tablets
600 tablets used for stability
568 are remaining</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>• Previously Reported in panel inspection:
The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability & for Accelerated Stability studies)
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>
</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 Specifications and Testing Method of applied product and its validation data. • 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.	**Amlodipine as besylate:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 36 Months** (30°C±2°C & 65±5% RH) stability study reports of 03 batches **Olmesartan medoxomil** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 48 Months** (30°C±2°C & 65±5%RH) stability study reports of 03 batches **Hydrochlorothiazide:** The firm has submitted copy of **accelerated, 06 Months** (40°C ± 2°C & 75±5 % RH) &**long term, 48 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 refereed to the claimed that there composition is same as innovators and refereed to hand book of excipient.
18.	Record of comparative dissolution data.	• Firm has submitted Comparative dissolution study of their product Sofvasc trio with Innovator's Brand "Tribenzor" conducted on following dates: • Comparative dissolution studies have been performed in following media: **Olmesartan medoxomil:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **Amlodipine as besylate:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **Hydrochlorothiazide:** i. 0.01N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. • 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:
Dissolution parameters stated in finished product testing method, submitted along with stability studies data are recommended by USFDA.
Amlodipine Besylate/Hydrochlorothiazide/Olmesartan Medoxomil:
Tablet II (Paddle) 50 Phosphate Buffer, pH 6.8 900 5, 10, 15, 20, 30 and 45

Deficiency/Observation	**Response by Pharma.**
Qualification of qualified person not mentioned	------
COA of Impurity standard are not provided and some COA's of standards were purchased from different manufacture (TRC, Synpure labs, then the API manufacturer. Justify/clarify.	
COA of Impurity standard of amlodipine are not provided same is required.	------

Decision: Registration Board after thorough deliberation deferred the case for scientific justification of use of working standard from a manufacturer other than API manufacturer.

Case No. 06: Miscellaneous Cases:

1009.	Name and address of manufacturer / Applicant	M/s Aptly pharmaceuticals, 5 Km, Sargodha road Bypass, Faisalabad
	M/s Aptly Pharmaceuticals, 5-Km Sargodha-Sidhar Bypass Road, Faisalabad. (New License) CLB in its 265th meeting held on 9th & 10th August, 2018 has considered and approved the grant of Drug Manufacturing License (No.000887) by way of formulation with following five sections: **1.** Oral Liquid (General) Veterinary section **2.** Oral Liquid (General Antibiotic) Veterinary section **3.** Oral Powder (General) Veterinary section **4.** Oral Powder (General Antibiotic) Veterinary section **5. Oral Powder (Penicillin) Veterinary section (14 products/ 10 molecules)**	
	Brand Name +Dosage Form + Strength	Aoromox C-20 Powder
	Diary No. Date of R& I & fee	Dy.No.29934, 5-9-18, Rs. 20,000/-
	Composition	Each 100gm contain Amoxicillin Trihydrate....25 gm Colistin sulphat …80 MIU
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	500 gm, 1 kg, 2.5 kg, 5 kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Colimoxin Forte Oral Dry Powder (080961)
	GMP status	Last GMP Inspection Conducted on 6 August 2018 with conclusive remarks of good compliance for grant of drug manufacturer license by way of formulation in respect to following sections • Oral liquid General • Oral liquid antibiotic • Oral powder general • Oral powder antibiotic • Oral powder penicillin

	Remarks of the Evaluator.	
	Decision of 285: Approved with innovators specifications **Remarks of evaluator:** The Previous composition was different from Me too, The firm now provide the **form 5** in which the applied formulation is as under Each 100gm contain Amoxicillin Trihydrate....20 gm Colistin sulphat …80 MIU Which is in line with **Me too** product: Colimoxin Forte Oral Dry Powder of Salmore Pharma (080961) Fee of 5000/- (Fee challan 0794611) dated 05/03/2019 is provided	
	Decision: Deferred for submission of full fee.	
1010.	Name and address of manufacturer / Applicant	M/s Aptly pharmaceuticals, 5 Km, Sargodha road Bypass, Faisalabad
	Brand Name +Dosage Form + Strength	Speclinomox Powder
	Diary No. Date of R& I & fee	Dy.No.29893, 5-9-18, Rs. 20,000/-
	Composition	Each kg contain Spectinomicin sulphate.. 8.8 gm Lincomycin HCL ……8.8 gm Amoxicillin Trihydrate....20 gm
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	500 gm, 1 kg, 2.5 kg, 5 kg Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Linkomox Oral Powder. (048226)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision of 285: Approved with innovators specifications **Remarks of evaluator:** The Previous composition was different from Me too, The firm now provide the **form 5** in which the applied formulation is as under Each 100 gm contain Spectinomicin sulphate.. 8.8 gm Lincomycin HCL ……8.8 gm Amoxicillin Trihydrate....20 gm Which is in line with **Me too** product: Linkomox Oral Powder of Biogen Pharma (048226) Fee of 5000/- (Fee challan 0794612) dated 05/03/2019 is provided	
	Decision: Deferred for submission of full fee.	

Case No. 01: Registration Aapplications of Newly Granted DML or New Section (Human)

a. M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore.

CLB in its 262nd meeting held 23-05-2018 has considered and approved the Tablet (Psychotropic) section. The details of molecules and products applied are as below:

Tablet (Psychotropic) Section : 10 molecules / 20 products		
1011.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Kalpax tablet 0.25mg
	Composition	Each tablet Contains: Alprazolam…..0.25mg
	Diary No. Date of R& I & fee	Dy. No 10634 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Leazam Tablet 0.25mg (Reg. 065304) of Leads Pharma
	GMP status	The firm was granted tablet (Psychotropic) section on the recommendation of panel of expert on dated 26-06-2018
	Remarks of the Evaluator.	
Decision: Approved		
1012.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Kalpax tablet 0.5mg
	Composition	Each tablet Contains: Alprazolam…..0.5mg
	Diary No. Date of R& I & fee	Dy. No 10632 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Zanac 0.5mg Tablet (Reg. 058628) of Zanctok Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1013.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Kalpax tablet 1mg
	Composition	Each tablet Contains: Alprazolam…..1mg
	Diary No. Date of R& I & fee	Dy. No 10630 Dated 02-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Lydia 1mg Tablet (Reg. 065699) of M/s. Wilshire Lab
	GMP status	The firm was granted tablet (Psychotropic) section on the recommendation of panel of expert on dated 26-06-2018

	Remarks of the Evaluator.	
	Decision: Approved	
1014.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Kalpax tablet 2mg
	Composition	Each tablet Contains: Alprazolam…..2mg
	Diary No. Date of R& I & fee	Dy. No 10631 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Onax 2 Tablet (Reg. 058450) of Safe Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1015.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Proraze tablet 1mg
	Composition	Each tablet Contains: Lorazepam…..1mg
	Diary No. Date of R& I & fee	Dy. No 10627 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ativan® C-IV of MEDA Manufacturing GmbH Cologne, Germany
	Me-too status	Veniti 1mg Tablet (Reg. 065694) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1016.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Proraze tablet 2mg
	Composition	Each tablet Contains: Lorazepam…..2mg
	Diary No. Date of R& I & fee	Dy. No 10617 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ativan® C-IV of MEDA Manufacturing GmbH Cologne, Germany
	Me-too status	Veniti 2mg Tablet (Reg. 065694) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1017.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Prodiaze tablet 2mg
	Composition	Each tablet Contains: Diazepam…..2mg
	Diary No. Date of R& I & fee	Dy. No 10628 Dated 02-03-2019, Rs. 20,000/-

	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DIAZEPAM TABLETS BP 2mg of Actavis UK Limited
	Me-too status	Anxosal 2mg Tablets (Reg. 064075) of Universal Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1018.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Prodiaze tablet 5mg
	Composition	Each tablet Contains: Diazepam…..5mg
	Diary No. Date of R& I & fee	Dy. No 10618 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DIAZEPAM TABLETS BP 5mg of Actavis UK Limited
	Me-too status	Rorpam 5mg Tablet (Reg. 080238) of Roryan Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1019.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Prodiaze tablet 10mg
	Composition	Each tablet Contains: Diazepam…..10mg
	Diary No. Date of R& I & fee	Dy. No 10626 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DIAZEPAM TABLETS BP 10mg of Actavis UK Limited
	Me-too status	Rorpam 10mg Tablet (Reg. 080239) of Roryan Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1020.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Clonamedics tablet 0.5mg
	Composition	Each tablet Contains: Clonazepam…..0.5mg
	Diary No. Date of R& I & fee	Dy. No 10633 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	KLONOPIN TABLETS (clonazepam) of Roche Pharma USA
	Me-too status	Clonazep 0.5 mg Tablets (Reg. 078588) of Roryan Pharma
	GMP status	As recorded for above application

	Remarks of the Evaluator.	
Decision: Approved		
1021.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Clonamedics tablet 1mg
	Composition	Each tablet Contains: Clonazepam…..1mg
	Diary No. Date of R& I & fee	Dy. No 10625 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	KLONOPIN TABLETS (clonazepam) of Roche Pharma USA
	Me-too status	Curo 1mg Tablets (Reg. 065700) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1022.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Clonamedics tablet 2mg
	Composition	Each tablet Contains: Clonazepam…..2mg
	Diary No. Date of R& I & fee	Dy. No 10624 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	KLONOPIN TABLETS (clonazepam) of Roche Pharma USA
	Me-too status	Clonazep 2 mg Tablets (Reg. 078589) of Roryan Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1023.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Bromakal tablet 1.5mg
	Composition	Each tablet Contains: Bromazepam…..1.5mg
	Diary No. Date of R& I & fee	Dy. No 10622 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Anxiolytic agents
	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.	Apo-Bromazepam 1.5mg of APOTEX INC.Toronto,
	Me-too status	E-Ze 1.5mg Tablet (Reg. 061254) of Genix Karachi
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved with innovator's specification		
1024.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Bromakal tablet 3mg
	Composition	Each tablet Contains: Bromazepam…..3mg
	Diary No. Date of R& I & fee	Dy. No 10621 Dated 05-03-2019, Rs. 20,000/-

	Pharmacological Group	Anxiolytic agents
	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.	Apo-Bromazepam 3mg of APOTEX INC.Toronto,
	Me-too status	Yazd 3mg Tablet (Reg. 065692) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved with innovator's specification		
1025.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Bromakal tablet 6mg
	Composition	Each tablet Contains: Bromazepam…..6mg
	Diary No. Date of R& I & fee	Dy. No 10620 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Anxiolytic agents
	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.	Apo-Bromazepam 6mg of APOTEX INC.Toronto,
	Me-too status	Tanil-6mg Tablet (Reg. 060760) of M/s Friends Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved with innovators specification		
1026.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Paradeine tablet
	Composition	Each tablet Contains: Paracetamol….500mg Codeine phosphate….15mg
	Diary No. Date of R& I & fee	Dy. No 10616 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	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.	Co-codamol 15/500 Tablets of Zentiva Pharma UK Limited
	Me-too status	Lowmol Tablets (Reg. 040426) of Lowit Pharma (Pvt) Ltd.,
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1027.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Zolkalp tablet 10mg
	Composition	Each film coated tablet Contains: Zolpidem tartrate…..10mg
	Diary No. Date of R& I & fee	Dy. No 10629 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives (Sedative hypnotic)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zolpidem 10 mg Film-Coated Tablets of Generics [UK] Ltd t/a Mylan
	Me-too status	Somnia 10mg Tablets (Reg. 067737) of M/s. Wilshire Lab.

	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1028.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Methylkal tablet 10mg
	Composition	Each tablet Contains: Methylphenidate hydrochloride…..10mg
	Diary No. Date of R& I & fee	Dy. No 10623 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Centrally acting sympathomimetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Medikinet® 10 mg tablet of MEDICE Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37, 58638 Iserlohn, Germany
	Me-too status	Fanidan Tablet 10 mg (Reg. 066475) of Danas Pharma.
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1029.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Phenokal tablet 30mg
	Composition	Each tablet Contains: Phenobarbitone…..30mg
	Diary No. Date of R& I & fee	Dy. No 10635 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PHENOBARBITAL ACCORD TABLETS BP 30mg of Accord-UK Ltd
	Me-too status	Phenotone Tablets (Reg. 065717) of M/s Rasco Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved		
1030.	Name and address of manufacturer / Applicant	M/s Perfect Pharma Pvt. Ltd. 5-km, Manga Road, Raiwind Lahore
	Brand Name +Dosage Form + Strength	Midakal tablet 7.5mg
	Composition	Each film coated tablet Contains: Midazolam…..7.5mg
	Diary No. Date of R& I & fee	Dy. No 10621 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dormicum 7.5 mg, film-coated tablets of Roche Nederland
	Me-too status	Phenotone Tablets (Reg. 065717) of M/s Rasco Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
Decision: Approved with innovator's specification		

M/s Hiranis Pharmaceuticals, Karachi .

CLB in its 269nd meeting held 26-02-2019 has considered and approved the Tablet (Psychotropic) section. The details of molecules and products applied are as below:

Tablet (Psychotropic) Section: 9 molecules / 20 products		
1031.	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	ANZILUM Tablet 0.25mg
	Composition	Each tablet contains:- Alprazolam……0.25mg
	Diary No. Date of R& I & fee	Dy. No 10947 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Leazam Tablet 0.25mg (Reg. 065304) of Leads Pharma
	GMP status	Last GMP inspection conducted on 29-01-2019, and the report concludes that the firm is overall GMP compliant.
	Remarks of the Evaluator	
	Decision: Approved	
1032.	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	ANZILUM Tablet 0.5mg
	Composition	Each tablet contains:- Alprazolam……0.5mg
	Diary No. Date of R& I & fee	Dy. No 10948 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Zanac 0.5mg Tablet (Reg. 058628) of Zanctok Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1033.	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	ANZILUM Tablet 1mg
	Composition	Each tablet contains:- Alprazolam……1mg
	Diary No. Date of R& I & fee	Dy. No 10949 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Lydia 1mg Tablet (Reg. 065699) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1034.	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	ANZILUM Tablet 2mg

	Composition	Each tablet contains:- Alprazolam……2mg
	Diary No. Date of R& I & fee	Dy. No 10950 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	XANAX® Pharmacia & Upjohn Company LLC USA
	Me-too status	Onax 2 Tablet (Reg. 058450) of Safe Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1035.	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	Lonza Tablet 0.5mg
	Composition	Each tablet contains: Lorazepam……0.5mg
	Diary No. Date of R& I & fee	Dy. No 10944 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ativan® C-IV of MEDA Manufacturing GmbH Cologne, Germany
	Me-too status	Veniti 0.5mg Tablet (Reg. 071220) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1036.	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	Lonza Tablet 1mg
	Composition	Each tablet contains: Lorazepam……1mg
	Diary No. Date of R& I & fee	Dy. No 10945 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ativan® C-IV of MEDA Manufacturing GmbH Cologne, Germany
	Me-too status	Veniti 1mg Tablet (Reg. 065694) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1037.	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	Lonza Tablet 2mg
	Composition	Each tablet contains: Lorazepam……2mg
	Diary No. Date of R& I & fee	Dy. No 10946 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in	Ativan® C-IV of MEDA Manufacturing GmbH Cologne,

	Reference Regulatory Authorities.	Germany
	Me-too status	Veniti 2mg Tablet (Reg. 065694) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1038.	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	Somno Tablet 5mg
	Composition	Each film coated tablet contains: Zolpidem Tartrate …… 5mg
	Diary No. Date of R& I & fee	Dy. No 10937 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives (Sedative hypnotic)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ambien of Sanofi Aventis, USFDA
	Me-too status	Demtrat Tablet 5mg of Bosch (Reg 061072)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1039.	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	Somno Tablet 10mg
	Composition	Each film coated tablet contains: Zolpidem Tartrate …… 10mg
	Diary No. Date of R& I & fee	Dy. No 10938 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives (Sedative hypnotic)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ambien of Sanofi Aventis, USFDA
	Me-too status	Zolpidem 10mg Tablet (Reg. No. 061008) of Medimarker's Hyderabad
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1040.	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	Mazinil Tablet 3mg
	Composition	Each tablet contains:- Bromazepam……3mg
	Diary No. Date of R& I & fee	Dy. No 10942 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Anxiolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Apo-Bromazepam 3mg of APOTEX INC.Toronto,
	Me-too status	Yazd 3mg Tablet (Reg. 065692) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	

1041.	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	Mazinil Tablet 6mg
	Composition	Each tablet contains:- Bromazepam……6mg
	Diary No. Date of R& I & fee	Dy. No 10943 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Anxiolytic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Apo-Bromazepam 6mg of APOTEX INC.Toronto,
	Me-too status	Tanil-6mg Tablet (Reg. 060760) of M/s Friends Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1042.	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	Clotril Tablet 0.5mg
	Composition	Each tablet contains: Clonazepam……0.5mg
	Diary No. Date of R& I & fee	Dy. No 10939 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	KLONOPIN TABLETS (clonazepam) of Roche Pharma USA
	Me-too status	Clonazep 0.5 mg Tablets (Reg. 078588) of Roryan Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1043.	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	Clotril Tablet 1mg
	Composition	Each tablet contains: Clonazepam……1mg
	Diary No. Date of R& I & fee	Dy. No 10940 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	KLONOPIN TABLETS (clonazepam) of Roche Pharma USA
	Me-too status	Curo 1mg Tablets (Reg. 065700) of M/s. Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1044.	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	Clotril Tablet 2mg
	Composition	Each tablet contains: Clonazepam……2mg
	Diary No. Date of R& I & fee	Dy. No 10941 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5

	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	KLONOPIN TABLETS (clonazepam) of Roche Pharma USA
	Me-too status	Clonazep 2 mg Tablets (Reg. 078589) of Roryan Pharma
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1045.	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	ESILGAN Tablet 1mg
	Composition	Each tablet contains:- Estazolam……1mg
	Diary No. Date of R& I & fee	Dy. No 10951 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Prosom Tab of Abbott, USFDA
	Me-too status	Esilgan Tablet 1mg of Helix (Reg#007480)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1046.	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	ESILGAN Tablet 2mg
	Composition	Each tablet contains:- Estazolam……2mg
	Diary No. Date of R& I & fee	Dy. No 10952 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Prosom Tab of Abbott, USFDA
	Me-too status	Esilgan Tablet 1mg of Helix (Reg#007480)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1047.	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	Slorit-D Tablet 2.5/120
	Composition	Each tablet contains:- Desloratadine……2.5mg Pseudoephedrine Sulfate…..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10953 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067246)
	GMP status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division	
1048.	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	Slorit-D Tablet 5/240
	Composition	Each tablet contains:- Desloratadine……5mg Pseudoephedrine Sulfate…..240mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10955 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic Amine
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CLARINEX-D of MSD, USFDA
	Me-too status	DESRHIN Tab of Atco (Reg#067247)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division	
1049.	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	Laderfex-D Tablet 60/120
	Composition	Each tablet contains:- Fexofendine HCl…….60mg Pseudoephedrine HCl……..120mg (Extended Release)
	Diary No. Date of R& I & fee	Dy. No 10954 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	Antihistamine/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D Tab of Sanofi Aventis, USFDA
	Me-too status	Fenadrin D Tablet of Noa Hemis (Reg#042352)
	GMP status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division	
1050.	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	Hirafen-Plus Tablet 200mg/30mg
	Composition	Each film coated tablet contains:- Ibuprofen……200mg Pseudoephedrine HCl……..30mg
	Diary No. Date of R& I & fee	Dy. No 10824 Dated 05-03-2019, Rs. 20,000/-
	Pharmacological Group	NSAID/Sympathomimetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Advil Cold and Sinus of Pfizer, USFDA
	Me-too status	Rovinac Tablets of Rock Pharma (Reg# 064206)
	GMP status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of requisite manufacturing facility/section from licensing division	

M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad

CLB in its 267th meeting held 31-12-2018 has considered and approved the one additional section of Liquid vial SVP (X-ray contrast media) Section. The details of molecules and products applied are as below:

Liquid Vial SVP (X-ray Contrast Media) 08 Products / 05 molecules		
1051.	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	Gadomag Injection
	Composition	Each ml vial Contains: Gadopenteate dimeglumine…….0.469g
	Diary No. Date of R& I & fee	Dy. No 40135 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Radiopaque diagnostic agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml, 15ml, 20ml & 100ml vial / MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAGNEVIST (GADOPENTETATE DIMEGLUMINE) of Bayer HealthCare Pharmaceuticals
	Me-too status	Omnivist 10ml Injection. Each Ml Contains:- Gadopentetate Dimeglumine 469mg Of Graton Pharma, Karachi.
	GMP status	New section for Liquid vial SVP(X-ray contrast media) letter issued by DRAP dated 17th January 2019
	Remarks of the Evaluator.	
	Decision: Approved	
1052.	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	Uroimag 76% injection
	Composition	Each ml Contains: Amidotrizoate meglumine …… 660mg Sodium amidotrizoate …….. 100mg
	Diary No. Date of R& I & fee	Dy. No 40144 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Diagnostic contrast media
	Type of Form	Form 5
	Finished Product Specification	Rotex Specs.
	Pack size & Demanded Price	Pack of 20's, 50's & 100's / MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	UROGRAFIN of Bayer plc 400 South Oak Way
	Me-too status	
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	
1053.	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	Ioimag – 300 Injection
	Composition	Each ml contains 612mg Iopamidol equivalent to 300mg of iodine per ml.
	Diary No. Date of R& I & fee	Dy. No 40160 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Radiopaque diagnostic agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Pack of 20ml, 50ml & 100ml / MRP. Rs. As per SRO

	Approval status of product in Reference Regulatory Authorities.	NIOPAM 300, solution for injection of Bracco Imaging spa. Via Egidio Folli 50 20134 Milano - Italy
	Me-too status	SCANLUX 300MG/ML SOLUTION FOR INJECTION of M/s HAJI MEDICINE CO., RAWALPINDI
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1054.	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	Ioimag – 370 Injection
	Composition	Each ml contains 755mg Iopamidol equivalent to 370mg of iodine per ml.
	Diary No. Date of R& I & fee	Dy. No 40180 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Radiopaque diagnostic agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Pack of 20ml, 50ml & 100ml MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	NIOPAM 370, solution for injection of Bracco Imaging spa Via Egidio Folli 50 20134 Milano – Italy
	Me-too status	Pamiray 370 inj. Of Al-Habib Pharma Karachi
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1055.	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	Iovist -300 Injection
	Composition	Each ml contains 623mg Iopromide equivalent to 300mg of Iodine per ml
	Diary No. Date of R& I & fee	Dy. No 40134 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Radiopaque diagnostic agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Pack of 20ml, 50ml & 100ml MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultravist -300 Injection of Bayer Health Care Germany
	Me-too status	Ultravist-300 Injection Contains: Iopromide…0.623gm of M/s Ali Gohar & Co. Karachi
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1056.	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	Iovist -370 Injection
	Composition	Each ml contains 768.86mg Iopromide equivalent to 370mg of Iodine per ml
	Diary No. Date of R& I & fee	Dy. No 40201 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Radiopaque diagnostic agent
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Pack of 20ml, 50ml & 100ml / MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ultravist -370 Injection of Bayer Health Care Germany
	Me-too status	Ultravist 370 Injectioncontains: - IOPROMIDE…0.769gm of M/s ALI GOHAR & CO KARACHI

	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1057.	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	Hexoimag-300 Injection
	Composition	Each ml contains 647mg Iohexol equivalent to 300mg of Iodine per ml
	Diary No. Date of R& I & fee	Dy. No 40127 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Diagnostic contrast media
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Pack of 20ml, 50ml & 100ml MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omnipaque -300 inj. GE Healthcare Ireland Limited, Cork, Ireland
	Me-too status	OMNIPAQUE INJECTION 300MG/MLCONTAINS: - IOHEXOL 647.1MG of M/s APEX PVT LTD KARACHI
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1058.	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	Hexoimag-350 Injection
	Composition	Each ml contains 755mg Iohexol equivalent to 350mg of Iodine per ml
	Diary No. Date of R& I & fee	Dy. No 40179 Dated 05-12-2018, Rs. 20,000/-
	Pharmacological Group	Diagnostic contrast media
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	Pack of 20ml, 50ml & 100ml MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omnipaque -350 inj. GE Healthcare Ireland Limited, Cork, Ireland
	Me-too status	Monopaque 350mg/ml Injection of Graton Pharma,
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	

M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad (duplicate dossier)

New Section for sterile dry powder vial and sterile liquid ampoule (Steroid) inspected by panel of expert on dated 19th Sep. 2018 and panel recommended the grant of applied new/additional sections.

Liquid Ampoule (Steroid) 5 products/ 4 molecules		
1059.	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	DEPO-MED 40MG/ML INJECTION
	Composition	Each 1ml Ampoule Contains; Methylprednisolone acetate ……40mg
	Diary No. Date of R& I & fee	Dy. No 4339 Dated 23-04-2019, Rs. 20,000/- dated 04-12-2018
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	1 Amp x 1ml / MRP As per SRO
	Approval status of product in Reference Regulatory Authorities.	Depo-Medrone Injection 40mg/1ml by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Co-Sterol Injection of Cirin Pharma (63094)
	GMP status	New Section for sterile dry powder vial and sterile liquid ampoule (Steroid) inspected by panel of expert on dated 19th Sep. 2018 and panel recommended the grant of applied section.
	Remarks of the Evaluator.	
	Decision: Approved with change in brand name	
1060.	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	DEPO-MED 80MG/2ML INJECTION
	Composition	Each 2ml Ampoule Contains; Methylprednisolone acetate ……80mg
	Diary No. Date of R& I & fee	Dy. No 4330 Dated 23-04-2019, Rs. 20,000/- dated 04-12-2018
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1 Amp x 2ml / MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Depo-Medrone Injection 80mg/2ml by M/s Pfizer Limited (MHRA Approved)
	Me-too status	ROTAPRED DEPOT INJECTION 80MG of ROTEX (12174)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with change in brand name	
1061.	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	TRIMACORT 40MG INJECTION
	Composition	Each 1ml ampoule contains: Triamcinolone acetonide ……40mg
	Diary No. Date of R& I & fee	Dy. No 4336 Dated 23-04-2019, Rs. 20,000/- dated 04-12-2018
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1 Amp x1ml / MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	KENACORT A40 triamcinolone acetonide 40mg/1ml injection ampoule by M/s Aspen Pharma (Pvt) Ltd (TGA Approved)
	Me-too status	Lisanolona 40mg/1ml injection (ampoule) by M/s Mehran International (Reg. # 039871)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with change in brand name	
1062.	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	DEPO MEDROX 150MG/ML INJECTION
	Composition	Each 1ml Ampoule Contains; Medroxyprogesterone acetate ……150mg
	Diary No. Date of R& I & fee	Dy. No 4338 Dated 23-04-2019, Rs. 20,000/-
	Pharmacological Group	Synthetic progestogen
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1 Amp x1ml / MRP. Rs. As per SRO

	Approval status of product in Reference Regulatory Authorities.	Depo-Provera (1ml) 150mg/1ml Sterile Suspension for injection (1ml) by M/s Pfizer, UK (MHRA Approved)
	Me-too status	MEGESTRON INJ of ORGANON (Reg. 12656)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with change in brand name	
1063.	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	DEXASONE 4MG/ML INJECTION
	Composition	Each 1ml Ampoule Contains; Dexamethasone phosphate (as sodium) ……4mg
	Diary No. Date of R& I & fee	Dy. No 4337 Dated 23-04-2019, Rs. 20,000/- 04-12-2018
	Pharmacological Group	Glucocorticoid
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	25's Ampoule x 1ml / MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL DEXAMETHASONE SODIUM PHOSPHATE INJECTION 4mg/ml (as sodium) Injection Ampoule by M/s Hospira Australia Pvt Ltd
	Me-too status	D.Dron Injection of Epharm Laboratories (Reg. 058424)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	

REGAL Pharmaceuticals, Islamabad.

The CLB in its 269th meeting held on 26.02.2019 granted three additional section to the firm. The details of molecules and products applied are as below:

Dry Suspension Section (Cephalosporin): 7 molecules/ 13 Products		
1064.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ZOLEX 125mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cephalexin Monohydrate eq to Cephalexin USP… 125mg
	Diary No. Date of R& I & fee	Diary No 15108 Dated 07/03/2019, Rs 20000/- , Dated 06/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60 ml ; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefalexin 125mg/5ml Powder for Oral Suspension of M/s Milpharm Limited UK
	Me-too status	AG-CIN 125mg Dry Suspension (Saydon Pharma)
	GMP status	Grant of Additional Sections by CLB in its 269th meeting dated 26th Feb. 2019 are as under: 1. Capsule Section (Cephalosporin) 2. Dry Suspension Section (Cephalosporin) 3. Dry Powder vial Injection (Cephalosporin)
	Remarks of the Evaluator.	
	Decision: Approved	
1065.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ZOLEX 250mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cephalexin Monohydrate eq to Cephalexin USP… 250mg
	Diary No. Date of R& I & fee	Diary No 15107 Dated 07/03/2019, Rs 20000/- , Dated 07/03/2019

	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60 ml ; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefalexin 250mg/5ml Powder for Oral Suspension of M/s Milpharm Limited UK
	Me-too status	AG-CIN 250mg Dry Suspension (Saydon Pharma)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1066.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	CEFIX 100mg/5ml Dry Suspension
	Composition	Each 5ml contains after reconstitution: Cefixime trihydrate eq to cefixime USP…. 100 mg.
	Diary No. Date of R& I & fee	Diary No 15103, Dated 07/03/2019, Rs 20000/- Dated 06/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml granules for oral suspension (MHRA)
	Me-too status	EPAN 100mg/5ml Dry suspension (EPHARM Labs)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1067.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	CEFIX 200mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cefixime trihydrate eq to cefixime……. 200 mg.
	Diary No. Date of R& I & fee	Diary No 11345, Dated 05/03/2019, Rs 20000/- Dated 04/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixime for Oral Suspension of Aurobindo Pharma USA, Inc. U.
	Me-too status	EPAN 200mg/5ml Dry suspension (EPHARM Labs)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1068.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Reclor 125mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cefaclor monohydrate USP……. 125 mg.
	Diary No. Date of R& I & fee	Diary No 15106, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	60ml; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	125mg/5ml SUSPENSION (cefaclor) (MHRA)
	Me-too status	CECLOR 125mg/5ml ELI LILLY (Reg. 007176)
	GMP status	As recorded for above application

	Remarks of the Evaluator.	
	Decision: Approved	
1069.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Reclor 250mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cefaclor as monohydrate ……. 250 mg.
	Diary No. Date of R& I & fee	Diary No 15105, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	60ml; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	250mg/5ml SUSPENSION (cefaclor) (MHRA)
	Me-too status	CECLOR 125mg/5ml ELI LILLY (Reg. 007175)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1070.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Prolix 40mg/5ml Dry Suspension
	Composition	Each 5ml contains after reconstitution: Cefpodoxime proxetil eq to Cefpodoxime USP ….. 40mg.
	Diary No. Date of R& I & fee	Diary No 15109, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP Specification
	Pack size & Demanded Price	30ml and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefpodoxime 40 mg/5 ml granules for oral suspension of Milpharm Limited Ares, Odyssey Business Park West End Road South Ruislip HA4 6QD United Kingdom
	Me-too status	Podicef 40mg/5ml Dry Suspension of Mediate Pharma (R.#057919)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1071.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Prolix 50mg/5ml Dry Suspension
	Composition	Each 5ml contains after reconstitution: Cefpodoxime proxetil eq to Cefpodoxime USP ….. 50mg.
	Diary No. Date of R& I & fee	Diary No 15110 Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotics
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	30ml; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	cefpodoxime proxetil eq 50mg base/5ml of pharmacia and upjohn USFDA
	Me-too status	Qink 50mg/5ml Dry Suspension(Wilshire Labs)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1072.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Recef 250mg/5ml Dry Suspension

	Composition	Each 5ml after reconstitution contains: Cephradine as monohydrate eq to cephradine USP ….. 250mg.
	Diary No. Date of R& I & fee	Diary No 15112 Dated 07/03/2019, Rs 20000/- , Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	VELOSEF '250' of APOTHECON (USFDA)
	Me-too status	VELOSEF 250MG sus. (Reg. 1868) by Gsk
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1073.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	NEROX 125mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cefadroxil Monohydrate USP eq to Cefadroxil …… 125mg
	Diary No. Date of R& I & fee	Diary No 15113 Dated 07/03/2019, Rs 20000/- , Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60 ml ; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEFADROXIL/CEFADROXIL HEMIHYDRATE EQ 125MG BASE/5ML of APOTHECON
	Me-too status	Evacef Suspension 125mg of Highnoon Lab (Reg 11213)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1074.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	NEROX 250mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cefadroxil Monohydrate USP eq to Cefadroxil…… 250mg
	Diary No. Date of R& I & fee	Diary No 15114 Dated 07/03/2019, Rs 20000/- , Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60 ml ; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefadroxil 250 mg/5 ml granules for oral suspension (MHRA)
	Me-too status	Evacef Suspension 250mg of Highnoon Lab (Reg. 11214)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1075.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	CEFTEN 90mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Ceftibuten as dihydrate ……. 90 mg.
	Diary No. Date of R& I & fee	Diary No 15615 Dated 07/03/2019, Rs 20000/- , Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	As per Innovator
	Pack size & Demanded Price	30ml; and Price as per Policy
	Approval status of product in	CEDAX 90mg/5ml

	Reference Regulatory Authorities.	(Schering Corporation Miami Lakes, FL 33014, USA)
	Me-too status	XIGRIS 90mg/5ml Dry suspension (Wilshire Labs)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	
1076.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Prolix 100mg/5ml Dry Suspension
	Composition	Each 5ml after reconstitution contains: Cefpodoxime proxetil eq to cefpodoxime ….. 100mg.
	Diary No. Date of R& I & fee	Diary No 15111, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	30ml; and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEFPODOXIME PROXETIL EQ 100MG BASE/5ML FOR SUSPENSION;ORAL (USFDA)
	Me-too status	Qink 100mg/5ml Dry Suspension(Wilshire Labs)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	

REGAL. Pharmaceuticals, Islamabad.

The CLB in its 269th meeting held on 26.02.2019 granted three additional section to the firm. The details of molecules and products applied are as below:

Capsule Section (Cephalosporin): 6 molecules/ 10 Products		
1077.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Ceften 400mg Capsules
	Composition	Each Capsule contains: Ceftibuten as Dihydrate ……. 400mg.
	Diary No. Date of R& I & fee	Diary No 15076, Dated 07/03/2019, Rs 20000/-, Dated 07/03/2019
	Pharmacological Group	Cephalosporine
	Type of Form	Form 5
	Finished Product Specification	As per innovator
	Pack size & Demanded Price	10 Capsules and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEFTIBUTEN DIHYDRATE EQ 400MG BASE of SI PHARMS USFDA
	Me-too status	Xigris Capsule 400mg capsule Wilshire Lab
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	
1078.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Reclor 250mg Capsule
	Composition	Each Capsule contains: Cefaclor USP ….. 250mg.
	Diary No. Date of R& I & fee	Diary No 15118, Dated 07/03/2019, Rs 20000/-, Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	12's Blister and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEFACLOR EQ 250MG BASE of LILLY USFDA
	Me-too status	U-Saclor 250 mg Capsules of Usawa (Reg. 76821)

	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1079.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Reclor 500mg Capsule
	Composition	Each Capsule contains: Cefaclor as monohydrate ….. 500mg.
	Diary No. Date of R& I & fee	Diary No 15119, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12's Blister Capsule, Price as per Policy.
	Approval status of product in Reference Regulatory Authorities.	CEFACLOR EQ 500MG BASE of LILLY USFDA
	Me-too status	U-Saclor 500 mg Capsules of Usawa (Reg. 76822)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1080.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ZOLEX 250mg Capsule
	Composition	Each Capsule contains: Cephalexin Monohydrate eq to Cephalexin USP… 250mg
	Diary No. Date of R& I & fee	Diary No 15071, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12's & 10's Capsules/Blister and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEPHALEXIN EQ 250MG BASE of BELCHER PHARMS USFDA
	Me-too status	Vegzin Capsules of Vega Pharma (Reg. 78693)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1081.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	ZOLEX 500mg Capsule
	Composition	Each Capsule contains: Cephalexin Monohydrate eq to Cephalexin USP… 500mg
	Diary No. Date of R& I & fee	Diary No 15072, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12's & 10's Capsules/Blister and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEPHALEXIN EQ 500MG BASE of BELCHER PHARMS USFDA
	Me-too status	Vegzin Capsules of Vega Pharma (Reg. 78694)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1082.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	CEFIX 200mg Capsule
	Composition	Each Capsule contains: Cefixime trihydrate eq to cefixime……. 200 mg.

	Diary No. Date of R& I & fee	Diary No 15117, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	JP Specification
	Pack size & Demanded Price	5 Capsules/Blister & Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixima Normon 200 mg cápsulas of Laboratorios Normon, S.A. (Spanish medicine agency approved)
	Me-too status	Soxime 200mg Capsule of Swat Pharma (Reg. 060127)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1083.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	CEFIX 400mg Capsule
	Composition	Each Capsule contains: Cefixime trihydrate eq to cefixime……. 400 mg.
	Diary No. Date of R& I & fee	Diary No 15116, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotics
	Type of Form	Form 5
	Finished Product Specification	JP Specification
	Pack size & Demanded Price	5 Capsules/Blister and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	CEFIXIME 400MG capsule ALKEM LABS LTD USFDA
	Me-too status	Cefim Capsule 400mg of Hilton Pharma (19818)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1084.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Recef 250mg Capsule
	Composition	Each Capsule contains: Cephradine as monohydrate eq to cephradine USP….. 250mg.
	Diary No. Date of R& I & fee	Diary No 15074, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	12's capsule/Blister Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefradine 250mg Capsules (Athlone Pharmaceuticals Limited Ireland
	Me-too status	SN Sef 250mg Capsules of SNB Pharma (Pvt) Ltd (Reg. 77500)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1085.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Recef 500mg Capsule
	Composition	Each Capsule contains: Cephradine as monohydrate eq to cephradine USP….. 500mg.
	Diary No. Date of R& I & fee	Diary No 15073, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP. Specification
	Pack size & Demanded Price	12's Capsule/Blister, Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefradine 500mg Capsules (Athlone Pharmaceuticals Limited Ireland

	Me-too status	Velo 500 mg Capsule of Linta Pharmaceutics (Reg. 78187)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1086.	Name and address of manufacturer / Applicant	Regal. Pharmaceuticals, Plot No 2-A, Street No. S-5 National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	NEROX 500mg Capsule
	Composition	Each Capsule contains: Cefadroxil Monohydrate USP eq to Cefadroxil…… 500mg
	Diary No. Date of R& I & fee	Diary No 15075, Dated 07/03/2019, Rs 20000/- Dated 07/03/2019
	Pharmacological Group	Cephalosporine antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12's & 10's Capsules and Price as per Policy
	Approval status of product in Reference Regulatory Authorities.	Cefadroxil 500 mg Capsules (MHRA)
	Me-too status	Gabadrox 500mg Capsule of Gaba PharmaKar (Reg. 76273)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	

M/s Novex Pharmaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad (New License)

Drug Manufacturing License (DML) to issue to M/s Novex Pharaceuticals **by way of formulation** and granted (04) new section to the firm. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

Eye Drops Section 04 Products/04 Molecules		
1087.	Name and address of Manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novoprost 0.005% w/v Opthalmic Solution
	Composition	2.5ml Opthalmic Solution contains: Latanoprost……..….125µg.
	Diary No, Date of R & I & fee	Dy. No. 13678 dated 07-03-19 Rs20,000/-Dated 07-03-19
	Pharmacological Group	Prostaglandins
	Type of Form	Form-5
	Finished Product Specification	As per Innovator
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	**Xalatan 50 micrograms/ml eye drops solution** Pfizer Limited
	Me-too status	Hilatan M/s Himont Pharmaceuticals (Pvt) Ltd
	GMP Status	Panel inspection conducted on 12-02-2019 & 21-02-2019, and the report concludes that the panel unanimously Recommended M/s Novex Pharmaceuticals for the grant of DML for the following section: 1. Sterile SVP Liquid Infusion vial (General) 2. Sterile Liquid Ampoule (General) 3. Sterile Liquid Ampoule (Steroid) 4. Sterile Eye/Ear/Nasal Preparations (Steroid)
	Remarks of the Evaluator	
	Decision: Approved	
1088.	Name and address of Manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Moxoflow 0.5% Sterile Ophthalmic Solution
	Composition	Each ml Opthalmic Solution contains: Moxifloxacin Hydrochloride 5.45mg equivalent to

		Moxifloxacin……..…5mg.
	Diary No, Date of R & I & fee	Dy. No 13667 dated 07-03-19 Rs20,000/-Dated 07-03-19
	Pharmacological Group	Quinolone antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Moxivig 0.5%w/v Eye Drops, Solution Marketing Authorisation Holder Novartis Pharmaceuticals UK Limited
	Me-too status	A-Mox of M/S Atco Laboratories Ltd
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of requisite manufacturing facility from licensing division since the firm has Sterile Eye/Ear/Nasal Preparations (Steroid) section	
1089.	Name and address of Manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nobradex Sterile Ophthalmic Suspension
	Composition	Each ml Ophthalmic Solution contains: Tobramycin ……..….3 mg. Dexamethasone ……...1 mg
	Diary No, Date of R & I & fee	Dy. No. 13668 dated 07-03-19 Rs 20,000/-Dated 07-03-19
	Pharmacological Group	Water-Soluble Aminoglycoside Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	TOBRADEX 3mg/ml/1mg/ml Eye Drops, Suspension
	Me-too status	Bracin D Sterile Ophthalmic Suspension (Reg. 30904) of Atco.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1090.	Name and address of Manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novaket 0.5% w/v Ophthalmic Solution
	Composition	Each ml Opthalmic Solution contains: Ketorolac Tromethamine ……..…5mg.
	Diary No, Date of R & I & fee	Dy. No. 13675 dated 07-03-19 Rs20,000/-Dated 07-03-19
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished Product Specification	As per Innovator
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Acular Allergan Ltd. United Kingdom
	Me-too status	Kats Sterile Ophthalmic Solution of Medicaids (Pak) (R#058072)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of requisite manufacturing facility from licensing division since the firm has Sterile Eye/Ear/Nasal Preparations (Steroid) section	
Sterile Liquid Ampoule (Steroid) 6 Products/ 6 Molecules		
1091.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Dexalon 4mg/ml Injection
	Composition	Each ml contains: Dexamethasone as sodium phosphate…….4mg
	Diary No, Date of R & I & fee	Dy. No 14875 dated 07-03-19 Rs20,000/-Dated 06-03-19

	Pharmacological Group	Glucocorticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Decadron Injection Merck Pharma
	Me-too status	DECADRON INJ 4MG/ML of Merck Sharp
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1092.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novalon 4mg/ml Injection
	Composition	Each ml contains: Betamethasone as sodium phosphate…….4mg
	Diary No, Date of R & I & fee	Dy. No 14883 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Glucocorticoid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Betamethasone Injection RPH Pharmaceutical Sweden
	Me-too status	Benate Injection, M/s Neutro Pharma (Reg. 044617)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1093.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Progest 250mg/ml Injection
	Composition	Each ml contains: Progestrone……..250mg
	Diary No, Date of R & I & fee	Dy. No 14881 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Hormone
	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.	
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed. ii. Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
1094.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novacort 40mg/ml Injection
	Composition	Each ml contains: Triamcinolone Acetonide……..40mg
	Diary No, Date of R & I & fee	Dy. No 14893 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Kenalog Injection Apothecon Pharma Inc. USA
	Me-too status	Danacort 40mg/ml Injection of M/S Danas Pharma (R.#081431)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1095.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nedrol 40mg/ml Injection
	Composition	Each ml contains: Methylprednisolone Acetate……..40mg
	Diary No, Date of R & I & fee	Dy. No 14882 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Glucocorticoid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Depo-Medrol Injection Pfizer New York
	Me-too status	DEPOMEDROL 40MG INJ Of KURRAM IBD
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1096.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Testone 250mg Injection
	Composition	Each ml contains: Testosterone Propionate …….250mg
	Diary No, Date of R & I & fee	Dy. No 13669 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	anabolic Steroid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Sustanon 250 is a solution in oil. Each ampoule contains 1 ml arachis oil containing the following active substances: - 30 mg Testosterone propionate - 60 mg Testosterone phenylpropionate - 60 mg Testosterone isocaproate - 100 mg Testosterone decanoate
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed. ii. Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
	Sterile Liquid Ampoule (General) 11 Products/11 Molecules	
1097.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nofever 150mg/5ml Injection
	Composition	Each ml ampoule contains:

		Paracetamol …….150mg
	Diary No, Date of R & I & fee	Dy. No. 14864 dated 07-03-19 Rs 20,000/-Dated 06-03-19
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed. ii. Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
1098.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Gentox 80mg/2ml Injection
	Composition	Each 2ml ampoule contains: Gentamycin as sulfate…….80mg
	Diary No, Date of R & I & fee	Dy. No 14865 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	Lirin 80mg Injection of Zinta Pharma (Reg. 040098)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	Approval Status of product in Reference Regulatory Authorities is not confirmed.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
1099.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nalfin 10mg Injection
	Composition	Each ml ampoule contains: Nalbuphine HCl …….10mg
	Diary No, Date of R & I & fee	Dy. No. 14872 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Opioid analgesic
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Nubain Injection Par Pharm Inc USA
	Me-too status	Nalfy Injection of M/s Vision Pharma (Reg. 081912)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1100.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Renox 25mg Injection

	Composition	Each ml ampoule contains: Ranitidine HCl ……..25mg
	Diary No, Date of R & I & fee	Dy. No. 14874 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Zantac Injection Teligent Pharm Inc USA
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	i. Composition showed that API is Nalbuphine HCL whereas applied product is Ranitidine HCL. ii. Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Composition showed that API is Nalbuphine HCL whereas applied product is Ranitidine HCL clarify.**	
1101.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Mecob 500mcg Injection
	Composition	Each ml ampoule contains: Mecobalamin ……..500mcg
	Diary No, Date of R & I & fee	Dy. No. 14877 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Methycobal (PMDA)
	Me-too status	Neucobal Inj. (Reg. 074370)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1102.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novex-D Injection
	Composition	Each ml ampoule contains: Cholecalciferol ……..5mg
	Diary No, Date of R & I & fee	Dy. No. 14879 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Vitamin D3
	Type of Form	Form-5
	Finished Product Specification	Innovators
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Vitamin D3 Good (ANSM)
	Me-too status	Genvit-D 5mg Injection (Reg. 61284)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1103.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novatral 75mg/3ml Injection
	Composition	Each 3ml ampoule contains: Diclofenac sodium ……..75mg

	Diary No, Date of R & I & fee	Dy. No. 14885 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specificatios
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	DICLOFENAC 75MG/3ML SOLUTION FOR INJECTION (MHRA)
	Me-too status	ANAFENAX INJECTION 75MG (Reg. 10019)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1104.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novil 22.75mg/ml Injection
	Composition	Each ml contains: Pheniramine Maleate….22.75mg
	Diary No, Date of R & I & fee	Dy. No 14891 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Anti-Histamine
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	Avil (Reg. 000226)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm**	
1105.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	TRAMOX Injection
	Composition	Each 2ml ampoule contains: Tramadol HCl ……..100mg
	Diary No, Date of R & I & fee	Dy. No. 14892 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Opioid Analgesic
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Zydol Injection Grünenthal Ltd. United Kingdom
	Me-too status	Zultra Injection (Reg. 80059)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1106.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novecin 300mg Injection IV/IM
	Composition	Each ml ampoule contains: Lincomycin as HCl ……..300mg
	Diary No, Date of R & I & fee	Dy. No. 14894 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Lincosamide antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO

	Approval Status of product in Reference Regulatory Authorities.	Lincomycin Injection X-Gen Pharma Inc USA
	Me-too status	Mahacin Injection M/s Humayun International Pharma (Pvt) Ltd, 20 K M Satiana Road, Faisalabad
	GMP Status	As recorded for above application
	Remarks of the Evaluator	Covering letter showing that applied product is methylprednisolone acetate) whereas in form-5A it is Lincomycin.
	Decision: Deferred due to Covering letter showing that applied product is methylprednisolone acetate) whereas in form-5A it is Lincomycin clarify.	
1107.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novafer 100mg/5ml Injection
	Composition	Each 5ml ampoule contains: Iron sucrose complex ……..100mg
	Diary No, Date of R & I & fee	Dy. No. 147871 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Vonefer Injection Vifor France.
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	i. Composition submitted in form-5A shows paracetamol whereas covering letter shows Iron sucrose complex. ii. Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Incorrect composition.**	
	Sterile SVP Liquid Infusion vial (General) 8 Molecules / 9 Products	
1108.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Metox 500mg/100ml Injection
	Composition	Each 100ml vial contains: Metronidazole…….500mg
	Diary No, Date of R & I & fee	Dy. No. 14886 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	nitroimidazoles (Amoebicides)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml x1s (100ml Vial for injection) or , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Metronidazole 500 mg / 100 ml Intravenous Infusion by Baxter Healthcare Ltd UK
	Me-too status	Lomizole Infusion 500mg of Llyods Pharmaceutical (R.#032001)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1109.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nofever 1000mg/100ml Injection
	Composition	Each 100ml vial contains: Paracetamol……..……1000mg
	Diary No, Date of R & I & fee	Dy. No 14870 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	analgesics and antipyretics

	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	100ml x1's, As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Paraceatmol Injection Accord Healthcare Ltd UK (UK emc Approved)
	Me-too status	Paedal Infusion of M/s Regal Pharmaceuticals
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1110.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nofever 500mg/50ml Injection
	Composition	Each 50ml vial contains: Paracetamol……..…500mg
	Diary No, Date of R & I & fee	Dy. No 14869 dated 07-03-19 Rs20,000/-Dated 0-03-19
	Pharmacological Group	analgesics and antipyretics
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	50ml x1's , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Paracetamol Injection Accord Healthcare Ltd UK (UK emc Approved)
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **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 Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	NS 0.9% Injection
	Composition	Each 100ml injection contains: Sodium chloride….0.9g
	Diary No, Date of R & I & fee	Dy. No. 14867 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	B.P Specifications
	Pack Size & Demanded Price	100ml infusion, As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Sodium Chloride 0.9% Intravenous Infusion BP of Baxter Healthcare Ltd. Caxton Way, Thetford Norfolk IP24 3SE United Kingdom
	Me-too status	0.9% Sodium Chloride of Martin Dow Karachi (Reg. 021038)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1112.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Oflovex 200mg/100ml Injection
	Composition	Each 100ml vial contains: Ofloxacin…….200mg
	Diary No, Date of R & I & fee	Dy. No 14863 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	100ml x1's , As per SRO

	Approval Status of product in Reference Regulatory Authorities.	Tarivid Injection Sanofi-aventis Pharms UK
	Me-too status	Satacin Infusion I.V Injection (Reg. 71286) of Satum
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1113.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novecip 200mg/100ml Infusion
	Composition	Each vial contains: Ciprofloxacin…..……200mg
	Diary No, Date of R & I & fee	Dy. No 14880 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml x1's, As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Ciprofloxacin 2 mg/ml solution for infusion of Hikma Farmacêutica (Portugal), S.A UK.
	Me-too status	Efecip Infusion 200mg/100ml of Genix Karachi (Reg. 073466)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1114.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Levonox 500mg/100ml Infusion
	Composition	Each 100ml contains: Levofloxacin as Hemihydrate…..…..500mg
	Diary No, Date of R & I & fee	Dy. No 14878 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml x1's , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Levofloxacin 5 mg/ml Solution for Infusion of Hospira UK Limited
	Me-too status	Myroleve 500mg/100ml Infusion of Myrtle Pharma Karachi (Reg. 070629)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	
1115.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Flucoz 200mg/100ml Injection
	Composition	Each 100ml vial contains: Fluconazole……..……200mg
	Diary No, Date of R & I & fee	Dy. No 14868 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml x1's , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Diflucon 200mg/100ml Injection Pfizer Pharms USA
	Me-too status	
	GMP Status	As recorded for above application
	Remarks of the Evaluator	Generic/me-too) not confirmed from available data.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)**	

	alongwith registration number, brand name and name of firm	
1116.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novemox 400mg/250ml Infusion
	Composition	Each 250ml infection contains: Moxifloxacin as HCl…….400mg
	Diary No, Date of R & I & fee	Dy. No 14889 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	1s (250 Vial for injection) or , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Avelox 400 mg/250 ml solution for infusion of Bayer plc, 400 South Oak Way UK
	Me-too status	Moximed 400mg /250ml Infusion of Medimarker's Hyderabad (Reg. 061020)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved	

Case no. 06 Registration Applications of Import Cases:

a. New cases

M/s Servier Research and Pharmaceuticals (Pakistan) Lahore applied following imported human pharmaceutical products. The detail are as under:

1117.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., 65 Main Boulevard Gulberg, Lahore
	Detail of Drug Sale License	Address: M/s Servier Research Pharmaceuticals, Kot abdul malik ferozwala District Sheikhupura Status: License to Sell Drugs As a Distributor License no. 0011000 0002078 valid up to 28-06-2020
	Name and address of manufacturer	M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France
	Name and address of marketing authorization holder	M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 11654 Dated 10-08-2017
	Fee including differential fee	Rs. 50,000/- Dated 24-05-2017
	Brand Name +Dosage Form + Strength	CARIVALAN 6.25mg/5mg film coated tablets
	Composition	Each film coated tablet Contains: Carvedilol…….6.25mg Ivabradine…….5mg
	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Betablocker/ hyperpolarization-activated cyclic nucleotide-gated channel blocker
	Shelf life	24 months
	Demanded Price	
	Pack size	14, 28 & 56 Tablets
	International availability	France
	Me-too status	N/A
	Stability studies	Firm has submitted long term Provided data 18 months at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 026355) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-

		de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. • Original Notarized "Letter of Authorization" from M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France declaring M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., Pakistan as marketing authorization holder in aterritory defined as Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1118.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., 65 Main Boulevard Gulberg, Lahore
	Detail of Drug Sale License	Address: M/s Servier Research Pharmaceuticals, Kot abdul malik ferozwala District Sheikhupura Status: License to Sell Drugs as a Distributor License no. 0011000 0002078 valid up to 28-06-2020
	Name and address of manufacturer	M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France
	Name and address of marketing authorization holder	M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 11652 Dated 10-08-2017
	Fee including differential fee	Rs. 50,000/- Dated 24-05-2017
	Brand Name +Dosage Form + Strength	CARIVALAN 6.25mg/7.5mg film coated tablets
	Composition	Each film coated tablet Contains: Carvedilol…….6.25mg Ivabradine…….7.5mg
	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Betablocker/ hyperpolarization-activated cyclic nucleotide-gated channel blocker
	Shelf life	24 months
	Demanded Price	
	Pack size	14, 28 & 56 Tablets
	International availability	France
	Me-too status	N/A
	Stability studies	Firm has submitted long term Provided data 18 months at 30^0C±65%RH (two batches) and one batch 9month and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 026356) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. • Original Notarized "Letter of Authorization" from M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France declaring M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., Pakistan as marketing authorization holder in aterritory defined as Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1119.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., 65 Main Boulevard Gulberg, Lahore
	Detail of Drug Sale License	Address: M/s Servier Research Pharmaceuticals, Kot abdul malik ferozwala District Sheikhupura

		Status: License to Sell Drugs As a Distributor License no. 0011000 0002078 valid up to 28-06-2020
	Name and address of manufacturer	M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France
	Name and address of marketing authorization holder	M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 11651 Dated 10-08-2017
	Fee including differential fee	Rs. 50,000/- Dated 24-05-2017
	Brand Name +Dosage Form + Strength	CARIVALAN 12.5mg/7.5mg film coated tablets
	Composition	Each film coated tablet Contains: Carvedilol…….12.5mg Ivabradine…….7.5mg
	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Betablocker/ hyperpolarization-activated cyclic nucleotide-gated channel blocker
	Shelf life	24 months
	Demanded Price	
	Pack size	14, 28 & 56 Tablets
	International availability	France
	Me-too status	N/A
	Stability studies	Firm has submitted long term Provided data 18 months at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 026358) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. • Original Notarized "Letter of Authorization" from M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France declaring M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., Pakistan as marketing authorization holder in aterritory defined as Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1120.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., 65 Main Boulevard Gulberg, Lahore
	Detail of Drug Sale License	Address: M/s Servier Research Pharmaceuticals, Kot abdul malik ferozwala District Sheikhupura Status: License to Sell Drugs As a Distributor License no. 0011000 0002078 valid up to 28-06-2020
	Name and address of manufacturer	M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France
	Name and address of marketing authorization holder	M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 11655 Dated 10-08-2017
	Fee including differential fee	Rs. 50,000/- Dated 24-05-2017
	Brand Name +Dosage Form + Strength	CARIVALAN 25mg/5mg film coated tablets
	Composition	Each film coated tablet Contains: Carvedilol…….25mg Ivabradine…….5mg

	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Betablocker/ hyperpolarization-activated cyclic nucleotide-gated channel blocker
	Shelf life	24 months
	Demanded Price	
	Pack size	14, 28 & 56 Tablets
	International availability	France
	Me-too status	N/A
	Stability studies	Firm has submitted long term Provided data 18 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 026359) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. • Original Notarized "Letter of Authorization" from M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France declaring M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., Pakistan as marketing authorization holder in aterritory defined as Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1121.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., 65 Main Boulevard Gulberg, Lahore
	Detail of Drug Sale License	Address: M/s Servier Research Pharmaceuticals, Kot abdul malik ferozwala District Sheikhupura Status: License to Sell Drugs As a Distributor License no. 0011000 0002078 valid up to 28-06-2020
	Name and address of manufacturer	M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France
	Name and address of marketing authorization holder	M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 11650 Dated 10-08-2017
	Fee including differential fee	Rs. 50,000/- Dated 24-05-2017
	Brand Name +Dosage Form + Strength	CARIVALAN 25mg/7.5mg film coated tablets
	Composition	Each film coated tablet Contains: Carvedilol…….25mg Ivabradine…….7.5mg
	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Betablocker/ hyperpolarization-activated cyclic nucleotide-gated channel blocker
	Shelf life	24 months
	Demanded Price	
	Pack size	14, 28 & 56 Tablets
	International availability	France
	Me-too status	N/A
	Stability studies	Firm has submitted long term Provided data 18 months at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	Original Legalized CoPP (Certificate#. 026360) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France.

		• Original Notarized "Letter of Authorization" from M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France declaring M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., Pakistan as marketing authorization holder in aterritory defined as Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1122.	Name and address of Applicant	M/s Punjab Medical Services Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15133 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Gadotu 287mg/ml IV solution for Injection (10ml)
	Composition	Each ml vial Contains: Gadodiamide….287mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	MRI contrast agent
	Shelf life	24 months: Store at room temperature below 25^0C
	Demanded Price	As per SRO
	Pack size	10ml glass vial
	International availability	OMNISCAN™ (gadodiamide) Injection for Intravenous by M/s GE Healthcare Ireland Limited, Cork, Ireland
	Me-too status	OMNISCAN INJECTION (GADODIAMIDE 287MG/ML) Reg. 23181)
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• Original Legalized CoPP (Certificate#. 2018/1148) issued on 22-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 20/03/2020.. • Original Notarized "Letter of Authorization" from M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1123.	Name and address of Applicant	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center

		Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15134 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Gadotu 287mg/ml IV solution for Injection (20ml)
	Composition	Each ml vial Contains: Gadodiamide….287mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	**MRI** contrast agent
	Shelf life	24 months: Store at room temperature below 25^0C
	Demanded Price	As per SRO
	Pack size	20ml glass vial
	International availability	OMNISCAN™ (gadodiamide) Injection for Intravenous by M/s GE Healthcare Ireland Limited, Cork, Ireland
	Me-too status	OMNISCAN INJECTION (GADODIAMIDE 287MG/ML) Reg. 23181)
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1148)** issued on 22-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 20/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years.
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1124.	Name and address of Applicant	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15128 Dated 24-04-2018

	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Kopaq 300 I mg/ml IV solution for Injection (50ml)
	Composition	Each ml vial Contains: Iohexol….647mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	36 months: Store below 30^0C
	Demanded Price	As per SRO
	Pack size	50ml HP 756/100 Pen class of glass
	International availability	OMNIPAQUE Injection by M/s GE Healthcare Australia
	Me-too status	OMNIPAQUE INJECTION 300MG/ML of M/s APEX (Reg. 8867)
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1136)** issued on 22-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 20/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1125.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15126 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Kopaq 300 I mg/ml IV solution for Injection (100ml)
	Composition	Each ml vial Contains: Iohexol….647mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	36 months: Store below 30^0C

	Demanded Price	As per SRO
	Pack size	100ml HP 756/100 Pen class of glass
	International availability	OMNIPAQUE Injection by M/s GE Healthcare Australia
	Me-too status	Iobrix-350 Injection of M/s HOFFMANN (Reg. 32138)
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1136)** issued on 22-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 20/03/2020.. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1126.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15125 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Kopaq 350 I mg/ml IV solution for Injection (50ml)
	Composition	Each ml vial Contains: Iohexol….755mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	24 months: Store below 30°C
	Demanded Price	As per SRO
	Pack size	50ml sterile type I neutral glass vial
	International availability	OMNIPAQUE Injection by M/s GE Healthcare Australia
	Me-too status	OMNIPAQUE INJECTION 350MG/ML of M/s APEX (Reg. 8868)
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1138)** issued on 22-03-2018 by Republic of Turkey Ministry of Health

		Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 20/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1127.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15127 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Kopaq 350 I mg/ml IV solution for Injection (100ml)
	Composition	Each ml vial Contains: Iohexol….755mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	24 months: Store below 30^0C
	Demanded Price	As per SRO
	Pack size	100ml sterile type I neutral glass vial
	International availability	OMNIPAQUE Injection by M/s GE Healthcare Australia
	Me-too status	Iobrix-350 Injection of HOFFMANN (Reg. 32138)
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1138)** issued on 22-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 20/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years

	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1128.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15131 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Ravistu 300mg I/ml solution for Injection (50ml)
	Composition	Each ml vial Contains: Iopromide….623.4mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	24 months: Store below 30^0C
	Demanded Price	As per SRO
	Pack size	50ml glass vial
	International availability	Ultravist 300 (MHRA)
	Me-too status	
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1122)** issued on 21-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 21/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1129.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15132 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Ravistu 300mg I/ml solution for Injection (100ml)
	Composition	Each ml vial Contains: Iopromide….623.4mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	24 months: Store below 30^0C
	Demanded Price	As per SRO
	Pack size	100ml glass vial
	International availability	Ultravist 300 (MHRA)
	Me-too status	Ultravist ® 300 (Reg. 072542) of M/s. Medipharm.
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1122)** issued on 21-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 21/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1130.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 151129 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Ravistu 370mg I/ml solution for Injection (50ml)
	Composition	Each ml vial Contains: Iopromide….768.86mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	24 months: Store below 30^0C
	Demanded Price	As per SRO

	Pack size	50ml glass vial
	International availability	Ultravist 370 (MHRA)
	Me-too status	ULTRAVIST 370 (Reg. 9865) of ALI GOHAR & CO
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1124)** issued on 21-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 21/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	
1131.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Ja/a/Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey
	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 15130 Dated 24-04-2018
	Fee including differential fee	Rs. 100,000/- Dated 24-04-2018
	Brand Name +Dosage Form + Strength	Ravistu 370mg I/ml solution for Injection (100ml)
	Composition	Each ml vial Contains: Iopromide….768.86mg
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	X-ray contrast media
	Shelf life	24 months: Store below 30°C
	Demanded Price	As per SRO
	Pack size	100ml glass vial
	International availability	Ultravist 370 (MHRA)
	Me-too status	
	Stability studies	Firm has submitted long term (24 months) at 30±2°C RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2°C, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1124)** issued on 21-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no:

		1703 Gebze Kocaeli Turkey valid until 21/03/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years
	Remarks of the Evaluator.	
	Decision: Approved as per policy of inspection of manufacturer abroad	

b. Deferred Cases:

Following products of M/s Servier Research and Pharmaceuticals Pakistan Lahore deferred in 274th meeting of Registration Board. The detail are as under:

1132.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals Pakistan Private limited 65 Main Boulevard Gulberg, Lahore.
	Detail of Drug Sale License	Address: Servier Research and Pharmaceuticals Pakistan Private limited, 9km Lahore Sheikhupura road, near Dosaco chowk Kot Abdul Malik, Tehsil Ferozewala, District Sheikhupura Validity: 28/04/2019 Status: License to sell drugs in Pharmacy
	Name and address of manufacturer	M/s. Les Laboratoirie Industrie, 905, route de Saran 45520 Gidy, France.
	Name and address of Product License Holder	M/s Les Laboratories Servier -50 rue Carnot -92282 Suresnes Cedex-France
	Exporting Country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 386 Dated 05/05/2016
	Fee including differential fee	Rs. 50,000/- Dated 11/04/2016
	Brand Name +Dosage Form + Strength	Triveram 20mg/10mg/10mg Film coated tablets
	Composition	Each film coated tablets contains:- Atorvastatin calcium trihydrate…….21.64mg (Eq. to Atorvastatin…….20mg) Perindopril Arginine……..…10mg (Eq. to Perindopril……..6.79mg) Amlodipine beilate……..……..13.87mg (Eq. to amlodipine……...10mg)
	Pharmacological Group	(Statin/ACE Inhibitors/Calcium Antagonist)
	Finished Product Specification	In House
	Shelf life	2 years
	Pack size	30 tablets in HDPE bottle with dessicant
	Demanded Price	Not Proposed
	Intrnational availability	Available in France as per CoPP
	Me-too status	N/A
	Detail of certificates	Not provided
	Remarks of the Evaluator.	Following documents are not provided; 1. Original legalized CoPP 2. Stability data for zone IV-A 3. Approval status in reference regulatory authorities
	Orevious Decision: In 260th meeting Registration Board deferred the case for submission of original & legalized CoPP, approval status in reference authorities and stability data as per zone IV-A	
	Evaluation by PEC: The firm has submitted following documents:	

	1. Original & legalized CoPP (certificate No. 013199) issued by Commerce and Industry Chamber of Paris Ile de France region on 11/07/2017 describes that the facilities and operations conform to GMP as recommended by WHO. 2. The product is not available in exporting country for free sale, the reasons statedin CoPp are as follows; • The medicinal product has been reformulated in order to improve its stability under tropical conditions. • The medicinal product has been exclusively developed for the treatment of diseases, especially for tropical diseases, which are not endemic in the exporting country. • The medicinal product has been reformulated to exclude excipients which are not approved in the importing country. • The medicinal product has been reformulated to comply with a requirement regarding the dosage of an active ingredient • The medicinal product has a marketing authorization for another dose, another pharmaceutical form or a different formulation. However, the firm has quoted the decision of Registration Board: *"*if an imported drug is not on free sale in its respective country of origin /manufacture, such product will be registered in Pakistan if the product manufactured in the applied facility is approved by any of the regulatory authorities from USFDA, EMA, PMDA Japan, Australia TGA, Health Canada, Switzerland or any of regulatory authority of former erstwhile Westren Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or three stringent regulatory bodies of former erstwhile Eastren Europe. However, references countries regarding availability of drug / molecule /formulation shall remain the same as specified in 249th meeting of RegistrationBoard*''*. The firm has provided following reference where the product is registered, which have been verified. • Ireland (Triveram 20mg/10mg/10mg film-coated tablets) https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0568-028-004_24042017124231.pdf • Estonia (Triveram 20mg/10mg/10mg film-coated tablets) http://ravimiregister.ravimiamet.ee/en/default.aspx?pv=HumRavimid.Otsing • Poland (Triveram 20mg/10mg/10mg film-coated tablets) http://pub.rejestrymedyczne.csioz.gov.pl/(X(1)S(agwz3bqzsblyxdimdge4wuyd))/Rejestr.aspx?AspxAutoDetectCookieSupport=1#results 2. Stability data of 3 batches	
	Decision of 274th meeting of RB: *Deferred for submission of CoPP's of the countries where the product is registered for confirmation of free sale of the product.* Now the firm has submitted Original Legalized CoPP (Certificate#. 026370) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. **Decision : Approved as per policy of inspection of manufacturer abroad**	
1133.	Name and address of Applicant	M/s Servier Research and Pharmaceuticals Pakistan Private limited 65 Main Boulevard Gulberg, Lahore.
	Detail of Drug Sale License	Address: Servier Research and Pharmaceuticals Pakistan Private limited, 9km Lahore Sheikhupura road, near Dosaco chowk Kot Abdul Malik, Tehsil Ferozewala, District Sheikhupura Validity: 28/04/2019 Status: License to sell drugs in Pharmacy
	Name and address of manufacturer	M/s. Les Laboratoirie Industrie, 905, route de Saran 45520 Gidy, France.
	Name and address of Product License Holder	M/s Les Laboratories Servier -50 rue Carnot -92282 Suresnes Cedex-France
	Exporting Country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 384 Dated 05/05/2016
	Fee including differential fee	Rs. 50,000/- Dated 11/04/2016

Brand Name+Dosage Form + Strength	Triveram 10mg/5mg/5mg Film coated tablets
Composition	Each film coated tablets contains:- Atorvastatin calcium trihydrate……10.82mg (Eq. to Atorvastatin…….10mg) Perindopril Arginine……..…5mg (Eq. to Perindopril……..3.40mg) Amlodipine beilate……..……..6.94mg (Eq. to amlodipine……..5mg)
Pharmacological Group	(Statin/ACE Inhibitors/Calcium Antagonist)
Finished Product Specification	In House
Shelf life	2 years
Pack size	30 tablets in HDPE bottle with dessicant
Demanded Price	Not Proposed
Intrnational availability	Available in France as per CoPP
Me-too status	N/A
Detail of certificates	Not provided
Remarks of the Evaluator.	Following documents are not provided; 1. Original legalized CoPP 2. Stability data for zone IV-A 3. Approval status in reference regulatory authorities

Orevious Decision:

In 260th meeting Registration Board deferred the case for submission of original & legalized CoPP, approval status in reference authorities and stability data as per zone IV-A

Evaluation by PEC:

The firm has submitted following documents:

1. Original & legalized CoPP (certificate No. 013198) issued by Commerce and Industry Chamber of Paris Ile de France region on 11/07/2017 describes that the facilities and operations conform to GMP as recommended by WHO.

2. The product is not available in exporting country for free sale, the reasons statedin CoPp are as follows;

- The medicinal product has been reformulated in order to improve its stability under tropical conditions.
- The medicinal product has been exclusively developed for the treatment of diseases, especially for tropical diseases, which are not endemic in the exporting country.
- The medicinal product has been reformulated to exclude excipients which are not approved in the importing country.
- The medicinal product has been reformulated to comply with a requirement regarding the dosage of an active ingredient
- The medicinal product has a marketing authorization for another dose, another pharmaceutical form or a different formulation.

However, the firm has quoted the decision of Registration Board:

*"*if an imported drug is not on free sale in its respective country of **origin** /manufacture, such product will be registered in Pakistan if the product manufactured in the applied facility is approved by any of the regulatory authorities from USFDA, EMA, PMDA Japan, Australia TGA, Health Canada, Switzerland or any of regulatory authority of former erstwhile Westren Europe (United Kingdom, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland and Spain) or three stringent regulatory bodies of former erstwhile Eastren Europe. However, references countries regarding availability of drug / molecule /formulation shall remain the same as specified in 249th meeting of RegistrationBoard*''*.

The firm has provided following reference where the product is registered, which have been verified.

- Ireland (Triveram 10mg/5mg/5mg film-coated tablets) https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0568-028-001_24042017124311.pdf
- Estonia (Triveram 10mg/5mg/5mg film-coated tablets) http://ravimiregister.ravimiamet.ee/en/default.aspx?pv=HumRavimid.Otsing
- Poland (Triveram 10mg/5mg/5mg film-coated Tablets) http://pub.rejestrymedyczne.csioz.gov.pl/(X(1)S(agwz3bqzsblyxdimdge4wuyd))/Rejestr.aspx?AspxAutoDetectCookieSupport=1#results

	Stability data of 3 batches.
	Decision of 274th meeting of RB: *Deferred for submission of CoPP's of the countries where the product is registered for confirmation of free sale of the product* Now the firm has submitted Original Legalized CoPP (Certificate#. 026369) issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. **Decision: Approved as per policy of inspection of manufacturer abroad**.

Evaluator PEC-XI

Case No. 01: Registration applications for local manufacturing of (Human) Drugs.

a. New cases

1134.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Torsom Tablet 250mg
	Composition	Each film-coated tablet contains: Levetiracetam…….250mg
	Diary No. Date of R& I & fee	Dy No. 6970: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other antiepileptics
	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.	Levetiracetam 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	The firm has been granted GMP certificate on the basis of inspection dated 18.09.2018.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1135.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Torsom Tablet 500mg
	Composition	Each film-coated tablet contains: Levetiracetam…….500mg
	Diary No. Date of R& I & fee	Dy No. 6971: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other antiepileptics
	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.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1136.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Torsom Tablet 750mg
	Composition	Each film-coated tablet contains: Levetiracetam……750mg
	Diary No. Date of R& I & fee	Dy No. 6972: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other antiepileptics

	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.	Levetiracetam 750 mg film-coated tablets. MHRA approved
	Me-too status	Levotam film-coated 750mg Tablets. Reg. No. 55641
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1137.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Torsom XR Tablet 500mg
	Composition	Each extended release tablet contains: Levetiracetam……500mg
	Diary No. Date of R& I & fee	Dy No. 6973: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other antiepileptics
	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.	KEPPRA XR (levetiracetam) film-coated extended-release tablets, for oral use. **MHRA** approved
	Me-too status	Lerace XR Tablet. Reg. No. 70417
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1138.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Nofovir Tablet 300mg
	Composition	Each film-coated tablet contains: Tenofovir disproxil fumarate……..300mg
	Diary No. Date of R& I & fee	Dy No. 6952: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Anti-viral
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Viread 300mg Tablets. US-FDA approved
	Me-too status	Xenofovir Tablet. Reg. No. 81653
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1139.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Thickside Capsule 4mg
	Composition	Each capsule contains: Thiocolchicoside…….4mg
	Diary No. Date of R& I & fee	Dy No. 6951: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg capsule. ANSM approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	

1140.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Artist Tablet 80mg
	Composition	Each film-coated tablet contains: Telmisartan…….80mg
	Diary No. Date of R& I & fee	Dy No. 6963: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	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.	Telmark 80mg film-coated tablets. **MHRA** approved
	Me-too status	Tesart 80mg film-coated Tablets. Reg. No. 45083
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•.
	Decision: Approved.	
1141.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Artist Tablet 40mg
	Composition	Each film-coated tablet contains: Telmisartan…….40mg
	Diary No. Date of R& I & fee	Dy No. 6968: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	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.	Telmark 40mg film-coated tablets. **MHRA** approved
	Me-too status	Tesart 40mg film-coated Tablets. Reg. No. 45082
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1142.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Artist Tablet 20mg
	Composition	Each film-coated tablet contains: Telmisartan…….20mg
	Diary No. Date of R& I & fee	Dy No. 6967: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	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.	Telmark 20mg film-coated tablets. **MHRA** approved
	Me-too status	Pressurex 20mg film-coated Tablets. Reg. No. 67535
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1143.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Masaco Tablet 800mg
	Composition	Each extended release tablet contains: Mesalazine…….800mg
	Diary No. Date of R& I & fee	Dy No. 6962: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form 5

	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	ASACOL® HD (mesalamine) delayed-release tablets, for oral use. **MHRA** approved
	Me-too status	Masacol 800mg Tablet. Reg. No. 61348
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has mentioned film-coated tablet with seal coat and modified release coat. Upon clarification, the firm revised the coating to enteric coating without fee. However, the reference product has an outer protective coat consisting of a combination of acrylic based resins, Eudragit S (methacrylic acid and methyl methacrylate copolymer (1:2), NF) and Eudragit L (methacrylic acid and methyl methacrylate copolymer (1:1), NF). The inner coat consists of an acrylic based resin, Eudragit S, which dissolves at pH 7 or greater, releasing mesalamine in the terminal ileum and beyond for topical anti- inflammatory action in the colon.
	Decision: Deferred for clarification from the firm.	
1144.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Mesaco Tablet 400mg
	Composition	Each modified release tablet contains: Mesalazine…….400mg
	Diary No. Date of R& I & fee	Dy No. 6961: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Aminosalicylic acid and similar agents
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	ASACOL® HD (mesalamine) delayed-release tablets, for oral use. **MHRA** approved
	Me-too status	Coltab Tablet 400mg. Reg. No. 41652
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has mentioned film-coated tablet with seal coat and modified release coat. Upon clarification, the firm revised the coating to enteric coating without fee. However, the reference product has an outer protective coat consisting of a combination of acrylic based resins, Eudragit S (methacrylic acid and methyl methacrylate copolymer (1:2), NF) and Eudragit L (methacrylic acid and methyl methacrylate copolymer (1:1), NF). The inner coat consists of an acrylic based resin, Eudragit S, which dissolves at pH 7 or greater, releasing mesalamine in the terminal ileum and beyond for topical anti- inflammatory action in the colon.
	Decision: Deferred for clarification from the firm.	
1145.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vibes Tablet 7.5mg
	Composition	Each film-coated tablet contains: Ivabradine as HCl…….7.5mg
	Diary No. Date of R& I & fee	Dy No. 6966: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	CORLANOR film-coated tablets, for oral use. **USFDA** approved

	Me-too status	Ivatab 7.5mg Tablet. Reg. No. 76155
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	• **Decision: Approved with innovator's specifications.**	
1146.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vibes Tablet 5mg
	Composition	Each film-coated tablet contains: Ivabradine as HCl…….5mg
	Diary No. Date of R& I & fee	Dy No. 6965: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	CORLANOR film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Ivatab 5mg Tablet. Reg. No. 76154
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1147.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Change Tablet 5mg
	Composition	Each film-coated tablet contains: Escitalopram as oxalate…….5mg
	Diary No. Date of R& I & fee	Dy No. 6953: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	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.	Lexapro® (escitalopram) 5mg film-coated Tablets, for oral use. **USFDA** approved
	Me-too status	Dipgo Tablet 5mg, film-coated. Reg. No. 85714
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1148.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Merriot Tablet 30mg
	Composition	Each film-coated tablet contains: Mirtazapine…….30mg
	Diary No. Date of R& I & fee	Dy No. 6964: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other antidepressants
	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.	Remeron film-coated 30mg tablet. **USFDA** approved
	Me-too status	Remirta 30mg Tablet. Reg. No. 82606
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1149.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Merriot Tablet 15mg

	Composition	Each film-coated tablet contains: Mirtazapine…….15mg
	Diary No. Date of R& I & fee	Dy No. 6963: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other antidepressants
	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.	Remeron film-coated 15mg tablet. **USFDA** approved
	Me-too status	Remirta 15mg Tablet. Reg. No. 82605
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1150.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Urdoo Capsule 250mg
	Composition	Each capsule contains: Ursodeoxycholic acid…….250mg
	Diary No. Date of R& I & fee	Dy No. 6959: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	URSOFALK ursodeoxycholic acid 250mg capsule blister pack. **TGA** approved
	Me-too status	Rivsa 250mg Capsule. Reg. No. 82263
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1151.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Urdoo Capsule 500mg
	Composition	Each capsule contains: Ursodeoxycholic acid…….500mg
	Diary No. Date of R& I & fee	Dy No. 6960: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ursochol 500 mg capsule, hard. Swedish Medical Product Agency approved
	Me-too status	Rivsa 500mg Capsule. Reg. No. 82264
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1152.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bosten Tablet 62.5mg
	Composition	Each film-coated tablet contains: Bosentan as monohydrate…….62.5mg
	Diary No. Date of R& I & fee	Dy No. 6954: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in	TRACLEER® (bosentan) film-coated tablets, for oral use.

	Reference Regulatory Authorities.	USFDA approved
	Me-too status	Bsantan 62.5mg film-coated tablets. Reg. No. 84199
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1153.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Wemet Tablet 50/500mg
	Composition	Each film-coated tablet contains: Sitagliptin as phosphate monohydrate…….50mg Metformin HCl……500mg
	Diary No. Date of R& I & fee	Dy No. 6954: 23.02.2018 PKR 20,000/-: 23.02.2018
	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	As per DRAP Policy
	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	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1154.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Wemet Tablet 50/1000mg
	Composition	Each film-coated tablet contains: Sitagliptin as phosphate monohydrate…….50mg Metformin HCl……1000mg
	Diary No. Date of R& I & fee	Dy No. 6958: 23.02.2018 PKR 20,000/-: 23.02.2018
	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	As per DRAP Policy
	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	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1155.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cornil Tablet 10mg
	Composition	Each tablet contains: Nicorandil……10mg
	Diary No. Date of R& I & fee	Dy No. 6955: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	IKOREL Nicorandil 10mg un-coated tablet. **TGA** approved
	Me-too status	Nicodil 10mg Tablet. Reg. No. 83345
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	

1156.	Name and address of manufacturer / Applicant	Sigma Pharma International (Pvt) Ltd., Plot # E-50, North Western Industrial Zone, Bin Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Cornil Tablet 20mg
	Composition	Each tablet contains: Nicorandil……20mg
	Diary No. Date of R& I & fee	Dy No. 6956: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	IKOREL Nicorandil 20mg un-coated tablet. **TGA** approved
	Me-too status	Nicodil 20mg Tablet. Reg. No. 83346
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1157.	Name and address of manufacturer / Applicant	High-Q Pharmaceuticals Plot No. 224, Sector 23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Pramadol Tablet
	Composition	Each film-coated tablet contains: Tramadol HCl……37.5mg Paracetamol……..325mg
	Diary No. Date of R& I & fee	Dy No. 9075: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per leader price
	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 10.04.2018 with the Conclusion: "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator.	•
	Decision: Approved.	
1158.	Name and address of manufacturer / Applicant	AGP Limited B-23, SITE, Karachi
	Brand Name +Dosage Form + Strength	Rivarox 2.5mg tablet
	Composition	Each film-coated tablet contains: Rivaroxaban……..2.5mg
	Diary No. Date of R& I & fee	Dy No. 9767: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Factor Xa inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	14's; Rs. 3796.77/- 28's; Rs. 7213.54/-
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 2.5mg film-coated tablets. **USFDA** approved
	Me-too status	XARELTO 2.5MG TABLETS. Reg No. 74794
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	•
	Decision: Approved.	

1159.	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.
	Brand Name +Dosage Form + Strength	Spacinol Tablet 80/80mg
	Composition	Each sugar-coated tablet contains: Phloroglucinol hydrate…..80mg trimethylphloroglucinol ……..80mg
	Diary No. Date of R& I & fee	Dy No. 9282: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	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.	Phloroglucinol/Trimethylphloroglucinol Acino 62.233mg/ 80mg, coated tablet by ACINO France SAS. Approved by ANSM
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	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 specifications.	
1160.	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	Lotenol (0.5% w/v) Ophthalmic Suspension
	Composition	Each ml of suspension contains: Loteprednol etabonate…..5mg
	Diary No. Date of R& I & fee	Dy No. 6917: 23.02.2018 PKR 20,000/-: 21.02.2018
	Pharmacological Group	Corticosteroids, plain
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	2.5ml, 5ml, 10ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Lotemax ophthalmic suspension 0.5% (w/v). **USFDA** approved
	Me-too status	Lotepred Forte Ophthalmic Suspension 0.5%. Reg. # 67458
	GMP status	The firm was inspected on 16.02.2018, with the following conclusion: "In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other cGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an 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.	
1161.	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	Denide (0.05% w/w) Cream
	Composition	Each gram contains: Desonide…..0.5mg
	Diary No. Date of R& I & fee	Dy No. 6917: 23.02.2018 PKR 20,000/-: 21.02.2018
	Pharmacological Group	Corticosteroids, moderately potent (group II)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	10g, 15g, 60g; As per PRC

	Approval status of product in Reference Regulatory Authorities.	DESOWEN Desonide 0.5mg/g cream tube. **TGA** approved
	Me-too status	Stienoide Cream. Reg. # 46986
	GMP status	The firm was inspected on 16.02.2018, with the following conclusion: "In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other cGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an 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.	
1162.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd. Plot # A-248 & A-256 to A-259, HITE, Lasbela Balochistan, Pakistan
	Brand Name +Dosage Form + Strength	Ezibe 10mg Tablet
	Composition	Each tablet contains: Ezetimibe……..10mg
	Diary No. Date of R& I & fee	Dy No. 9510: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other lipid modifying agents
	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.	ZETIA (ezetimibe) Tablets. **USFDA** approved
	Me-too status	Ezemibe Tablets 10mg. Reg No. 35815
	GMP status	The firm was inspected on 15.03.2018, wherein GMP was rated as GOOD.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1163.	Name and address of manufacturer / Applicant	Next Pharmaceutical Products Private Limited Plot No 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Fexo Plus Tablet 60/120mg
	Composition	Each extend release tablet contains: Fexofenadine HCl…..60mg Pseudoephedrine HCl……120mg
	Diary No. Date of R& I & fee	Dy No. 2327: 17.01.2018 PKR 20,000/-: 16.01.2018 PKR 5,000/-: 01.01.2019
	Pharmacological Group	pseudoephedrine, combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 20's; As per decision of PRC
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA-D 12 HOUR Extended-Release Tablets. USFDA approved
	Me-too status	Fexet-D 60Mg/120Mg film-coated Tablets. Reg No. 39099 (data does not depict two layer tablet)
	GMP status	The firm was last inspected on 22.02.2018, wherein the panel stated the firm had four sections but only two sections (Tablet and capsules) are operational at the time of inspection, and rated the GMP compliance as satisfactory.
	Remarks of the Evaluator.	• The reference product is in the form of two layer extended release tablet. The firm revised formulation accordingly,

		along with submission of Rs. 5,000/-. • The firm was asked to provide proof of availability of manufacturing facility. The firm requested **for withdrawal** of the product due to non-availability of bilayer tablet machine.
	Decision: Registration Board acceded to request for withdrawl of application and it stands disposed off.	
1164.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Xyloaid 2% Injection with epinephrine (adrenaline) 1:200,000 (ampule)
	Composition	Each ml contains: Lidocaine HCl (as monohydrate)……..20mg Epinephrine as bitartrate……5mcg
	Diary No. Date of R& I & fee	Dy No. 9290: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	lidocaine, combinations
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml x50's; Rs.1277.47
	Approval status of product in Reference Regulatory Authorities.	XYLOCAINE® PARENTERAL SOLUTIONS (20mL vial, 10ml plastic ampule). Health Canada approved. However, it is not confirmed whether it is lidocaine HCl, lidocaine HCl monohydrate or lidocaine HCl as monohydrate.
	Me-too status	Lovocain 2% Injection. Reg. No. 48306 (5ml).
	GMP status	The firm was inspected on 16th-28th August, 2018 Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	• The me-too products contain epinephrine (with 5ml fill volume); however, the firm has applied for Epinephrine as bitartrate.
	Decision: Deferred for the following: • **Proof of me-too product approved by DRAP with same fill volume and same salt form.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board is required.**	
1165.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Xyloaid 2% Injection
	Composition	Each ml contains: Lidocaine HCl (as monohydrate)……..20mg
	Diary No. Date of R& I & fee	Dy No. 9287: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Local anesthetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml x50's; Rs.1258.41
	Approval status of product in Reference Regulatory Authorities.	Lidocaine 20 mg/ml solution for injection. **MHRA** approved
	Me-too status	GEE-Ligno Injection. Reg. No. 80834 (10ml)
	GMP status	The firm was inspected on 16th-28th August, 2018 Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	•
	Decision: Deferred as firm has already same formulation	

1166.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Xyloaid 2% Jelly for topical use
	Composition	Each gram contains: Lidocaine HCl as monohydrate……..20mg
	Diary No. Date of R& I & fee	Dy No. 9288: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Anesthetics for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	15gm; Rs.42.50
	Approval status of product in Reference Regulatory Authorities.	Xylocain® 2% gel. Approved in Norway
	Me-too status	Logel 2w/w. Reg. No. 40221
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Deferred as firm has already same formulation	
1167.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Xyloaid 4% Topical solution
	Composition	Each ml contains: Lidocaine HCl (as monohydrate)……..40mg
	Diary No. Date of R& I & fee	Dy No. 9289: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Anesthetics for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	50ml; Rs.63.14
	Approval status of product in Reference Regulatory Authorities.	XYLOCAINE 4% TOPICAL liqnocaine hydrochloride 40mg/mL solution bottle. TGA approved
	Me-too status	XYLOCAINE 4% TROPICAL SOL. Reg. No. 380
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Deferred as firm has already same formulation	
1168.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Xyloaid 5% Ointment
	Composition	Each gram contains: Lidocaine ……..50mg
	Diary No. Date of R& I & fee	Dy No. 9291: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Anesthetics for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20g; Rs.61.42
	Approval status of product in Reference Regulatory Authorities.	Lidocaine 5% m/m Ointment. **MHRA** approved
	Me-too status	Xylocaine 5% Ointment. Reg. No. 23075
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Deferred as firm has already same formulation	
1169.	Name and address of manufacturer / Applicant	M/s Fozan Pharmaceutical. 36-A, Industrial Estate, Hayatabad, Peshawar
	Brand Name +Dosage Form + Strength	Mecofoz Tablet
	Composition	Each sugar-coated tablet contains: Mecobalamin …….500µg
	Diary No. Date of R& I & fee	Dy No. 9760: 15.03.2018 PKR 20,000/-: 14.03.2018 PKR 5,000/-: 14.03.2019
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)

	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	3x10's, 10x10's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Methicobide tablet 500 mcg sugar-coated, by Daito Corporation. Approved by **PMDA** Japan
	Me-too status	Balin 500mcg Tablet (sugar-coated) by Cibex Pharma Karachi. Reg. No. 74877
	GMP status	The firm was inspected on 25.05.2018, wherein the GMP was reported satisfactory.
	Remarks of the Evaluator.	• The firm revised the formulation to sugar-coated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved	
1170.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Levecet Tablet 250mg
	Composition	Each film-coated tablet contains: Levetiracetam…….250mg
	Diary No. Date of R& I & fee	Dy No. 9794: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved	
1171.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Levecet Tablet 500mg
	Composition	Each film-coated tablet contains: Levetiracetam…….500mg
	Diary No. Date of R& I & fee	Dy No. 9795: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84220
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved	
1172.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Levecet Tablet 750mg
	Composition	Each film-coated tablet contains: Levetiracetam…….750mg
	Diary No. Date of R& I & fee	Dy No. 9796: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 750 mg film-coated tablets. **MHRA** approved
	Me-too status	Levotam film-coated 750mg Tablets. Reg. No. 55641
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved	
1173.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Glita Plus Tablet 50/500mg
	Composition	Each film-coated tablet contains: Sitagliptin as phosphate monohydrate…….50mg Metformin HCl……500mg
	Diary No. Date of R& I & fee	Dy No. 9792: 15.03.2018 PKR 20,000/-: 15.03.2018
	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	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 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
1174.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Glita Plus Tablet 50/1000mg
	Composition	Each film-coated tablet contains: Sitagliptin as phosphate monohydrate…….50mg Metformin HCl……1000mg
	Diary No. Date of R& I & fee	Dy No. 9791: 15.03.2018 PKR 20,000/-: 15.03.2018
	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	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 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
1175.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Airmax Tablet 5mg
	Composition	Each chewable tablet contains: Montelukast (as sodium)…….5mg
	Diary No. Date of R& I & fee	Dy No. 9798: 15.03.2018 PKR 20,000/-: 15.03.2018 PKR 5,000/-: 20.03.2019
	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® (montelukast sodium) Chewable Tablets. USFDA approved

	Me-too status	Nohist Chewable Tablet 5mg. Reg. No. 85712
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	• The firm revised the formulation to chewable tablets in line with the reference product along with submission of Rs. 5000/- fee.
	Decision: Approved	
1176.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Airmax Tablet 10mg
	Composition	Each film-coated tablet contains: Montelukast (as sodium)…….10mg
	Diary No. Date of R& I & fee	Dy No. 9797: 15.03.2018 PKR 20,000/-: 15.03.2018
	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.	Montelukast 10 mg film-coated tablets. **MHRA** approved
	Me-too status	Nohist Tablet 10mg. Reg. No. 85713
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved	
1177.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Blin Capsule 50mg
	Composition	Each capsule contains: Pregabalin…….50mg
	Diary No. Date of R& I & fee	Dy No. 9790: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Other antiepileptics
	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.	Alzain 50 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
1178.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Flix Capsule 150mg
	Composition	Each capsule contains: Fluconazole…….150mg
	Diary No. Date of R& I & fee	Dy No. 9790: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Antimycotics for systemic 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.	Fluconazole 150mg Capsules. **MHRA** approved
	Me-too status	Conza Capsule. Reg. No. 84049
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.

	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
1179.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Fude-H Cream
	Composition	Each gram of cream contains: Fusidic Acid……20mg Hydrocortisone……10mg
	Diary No. Date of R& I & fee	Dy No. 9789: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Corticosteroids, combinations with antibiotics
	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.	Fucidin H Cream by LEO Laboratories Limited. **MHRA** approved
	Me-too status	Hivate Cream by Saffron Pharma. Reg. No. 46432
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
1180.	Name and address of manufacturer / Applicant	Linta Pharmaceuticals (Pvt.) Limited, Plot No. 03, Street No. S-5, National Industrial Zone Rawat, Islamabad-Pakistan
	Brand Name +Dosage Form + Strength	Low-B Plus 50/12.5mg Tablet
	Composition	Each film-coated tablet contains: Losartan potassium……50mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy No. 9789: 15.03.2018 PKR 20,000/-: 15.03.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) 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.	FORTZAAR 50 mg / 12.5 mg film-coated tablets. **ANSM** approved
	Me-too status	Rosar-H Tablets. Reg. No. 64218
	GMP status	The firm was inspected on 12.06.2018, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	•
	Decision: Approved	
1181.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Fedsert Tablet 50mg
	Composition	Each film-coated tablet contains: Sertraline as HCl……50mg
	Diary No. Date of R& I & fee	Dy No. 9505: 14.03.2018 PKR 20,000/-: 14.03.2018
	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; As per DRAP policy
	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	The firm was inspected 30.01.2019 with the following conclusion and recommendations: Conclusion: 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 operating in satisfactory level of cGMP compliance. Recommendations: They are advised to:- 1- Further increase no of Pharmacist in production section. 2- Purchase another HPLC for tests and analysis. 3- Provide room for retention samples.
	Remarks of the Evaluator.	• The firm revised 'sertraline as HCl' to 'sertraline HCl' in Master formula only.
	Decision: Deferred for fee	
1182.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Fedsert Tablet 100mg
	Composition	Each film-coated tablet contains: Sertraline as HCl……100mg
	Diary No. Date of R& I & fee	Dy No. 9508: 14.03.2018 PKR 20,000/-: 14.03.2018
	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; As per DRAP policy
	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	As recorded for above application
	Remarks of the Evaluator.	• The firm revised 'sertraline as HCl' to 'sertraline HCl' in Master formula only.
	Decision: Deferred for fee	
1183.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Lorx Tablet 4mg
	Composition	Each film-coated tablet contains: Lornoxicam……4mg
	Diary No. Date of R& I & fee	Dy No. 9507: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's, 50's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	XEFO 4 mg film-coated tablets. **ANSM** approved
	Me-too status	Noxilor Tablet. Reg. No. 84039
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1184.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Lorx Tablet 8mg
	Composition	Each film-coated tablet contains: Lornaxicam……8mg
	Diary No. Date of R& I & fee	Dy No. 9503: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 20's, 30's, 50's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	NOXON 8 mg film-coated tablets. **AIFA** approved
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933

	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1185.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Levecet Tablet 250mg
	Composition	Each film-coated tablet contains: Levetiracetam…….250mg
	Diary No. Date of R& I & fee	Dy No. 9506: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1186.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Levecet Tablet 500mg
	Composition	Each film-coated tablet contains: Levetiracetam…….500mg
	Diary No. Date of R& I & fee	Dy No. 9504: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1187.	Name and address of manufacturer / Applicant	Winthrox Laboratories, (Pvt) Ltd., K-219-A, SITE, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Winfan-P Tablet 50mg
	Composition	Each film-coated tablet contains: Diclofenac potassium……50mg
	Diary No. Date of R& I & fee	Dy No. 6873: 22.02.2018 PKR 20,000/-: 21.02.2018 PKR 5,000/-: 08.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	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.	Diclofenac Potassium 50 mg film-coated Tablets. **MHRA** approved
	Me-too status	Arnil-P 50mg film-coated tablets. Reg # 82129
	GMP status	The firm was inspected on 14.09.2017, wherein the GMP of the firm was rated as GOOD.
	Remarks of the Evaluator.	• The firm revised the formulation to film-coated tablet with submission of Rs. 5,000/- fee.
	Decision: Approved	
1188.	Name and address of manufacturer / Applicant	Winthrox Laboratories, (Pvt) Ltd., K-219-A, SITE, Super Highway, Phase-II, Karachi, Pakistan

	Brand Name +Dosage Form + Strength	Windic Tablet 50mg
	Composition	Each enteric-coated tablet contains: Diclofenac sodium……50mg
	Diary No. Date of R& I & fee	Dy No. 6872: 22.02.2018 PKR 20,000/-: 21.02.2018 PKR 5,000/-: 08.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	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.	Diclofenac Sodium 50 mg gastro-resistant tablets. **MHRA** approved
	Me-too status	Diclopal 50mg delayed release tablet. Reg # 82298
	GMP status	The firm was inspected on 14.09.2017, wherein the GMP of the firm was rated as GOOD.
	Remarks of the Evaluator.	• The firm revised the formulation to enteric-coated tablet with submission of Rs. 5,000/- fee.
	Decision: Approved	
1189.	Name and address of manufacturer / Applicant	Winthrox Laboratories, (Pvt) Ltd., K-219-A, SITE, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Windic SR Tablet 100mg
	Composition	Each sustained release tablet contains: Diclofenac sodium……100mg
	Diary No. Date of R& I & fee	Dy No. 6874: 22.02.2018 PKR 20,000/-: 21.02.2018 PKR 5,000/-: 08.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	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.	Dicloflex Retard 100 mg prolonged release tablet. **MHRA** approved
	Me-too status	Diclorax 100mg Tablet. Reg. # 85498
	GMP status	The firm was inspected on 14.09.2017, wherein the GMP of the firm was rated as GOOD.
	Remarks of the Evaluator.	• The firm revised the formulation to sustained release tablet with submission of Rs. 5,000/- fee. • The revised coating composition has HPMC 15cp as binder. The reference product contains sub-coat of Copovidone and Sucrose, and Pigmented film coat of Opadry 02B24025. The dossier does not depict the same. • The firm was asked about the use of sustained release polymer in composition, i.e., how the drug release was sustained/extended. The firm did not justify the same. The firm has mentioned HMPC K100 and HPMC K4 as binder.
	Decision: Deferred for further clarification from the firm.	
1190.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Telmi Tablet 40mg
	Composition	Each tablet contains: Telmisartan……40mg
	Diary No. Date of R& I & fee	Dy No. 1096: 08.01.2018 PKR 20,000/-: 08.01.2018
	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.	Mirpresoc 40mg tablets. **MHRA** approved

	Me-too status	Mycardix 40mg Tablets. Reg. No. 44216
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	•
	Decision: Approved	
1191.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Telmi AM Tablet 40/5mg
	Composition	Each tablet contains: Amlodipine as Besylate…..5mg Telmisartan……40mg
	Diary No. Date of R& I & fee	Dy No. 1096: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain + Dihydropyridine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x7; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TWYNSTA® (telmisartan/amlodipine) 40/5mg tablets, for oral use. **USFDA** approved
	Me-too status	Amtas 5mg + 40mg Tablet. Reg. No. 66943
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	•
	Decision: Approved	
1192	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Vastafo 10mg
	Composition	Each film-coated tablet contains: Rosuvastatin as calcium…..10mg
	Diary No. Date of R& I & fee	Dy No. 1070: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	HMG CoA 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.	Crestor 10mg film-coated tablets. MHRA approved
	Me-too status	Rostat 10mg Tablet. Reg. No. 55730
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1193.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amodip Tablet 10/160mg
	Composition	Each film-coated tablet contains: Amlodipine (as besylate) …….10mg Valsartan…….160mg
	Diary No. Date of R& I & fee	Dy No. 9304: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensives
	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	Exforge film-coated tablet 10/160. **USFDA** approved

	Reference Regulatory Authorities.	
	Me-too status	VALTAN -M 170 PLUS TABLET. Reg. No. 77207
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1194.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amodip Tablet 5/160mg
	Composition	Each film-coated tablet contains: Amlodipine (as besylate) …….5mg Valsartan…….160mg
	Diary No. Date of R& I & fee	Dy No. 9305: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensives
	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.	Exforge film-coated tablet 5/160. **USFDA** approved
	Me-too status	VALTAN -M 165 PLUS TABLET. Reg. No. 77206
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1195.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amodip Tablet 5/80mg
	Composition	Each film-coated tablet contains: Amlodipine (as besylate) …….5mg Valsartan…….80mg
	Diary No. Date of R& I & fee	Dy No. 9303: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensives
	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.	Exforge film-coated tablet 5/80. **TGA** approved
	Me-too status	VALTAN -M 85 PLUS TABLET. Reg. No. 77204
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1196.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Revo Tablet 25mg
	Composition	Each film-coated tablet contains: Eltrombopag as olamine…….25mg
	Diary No. Date of R& I & fee	Dy No. 9300: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other systemic hemostatics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROMACTA® (eltrombopag asolamine) 25 mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	REVOLADE TABLETS 25MG. Reg. No. 69584

	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1197.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Revo Tablet 50mg
	Composition	Each film-coated tablet contains: Eltrombopag as olamine…….50mg
	Diary No. Date of R& I & fee	Dy No. 9306: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other systemic hemostatics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PROMACTA® (eltrombopag asolamine) 50 mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	REVOLADE TABLETS 50MG. Reg. No. 69585
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1198.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amlodip-H Tablet 10/12.5/160mg
	Composition	Each film-coated tablet contains: Amlodipine as besylate…10mg Valsartan…..160mg Hydrochlorthiazide……12.5mg
	Diary No. Date of R& I & fee	Dy No. 9302: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensive
	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.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved
	Me-too status	Exforge HCT 10/160/12.5MG film coated tablets by Novatris Pharma. Reg. No. 69550
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1199.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amlodip-H Tablet 5/12.5/160mg
	Composition	Each film-coated tablet contains: Amlodipine as besylate…5mg Valsartan…..160mg Hydrochlorthiazide……12.5mg
	Diary No. Date of R& I & fee	Dy No. 9307: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensive
	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.	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	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1200.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amlodip-H Tablet 5/25/160mg
	Composition	Each film-coated tablet contains: Amlodipine as besylate…5mg Valsartan…..160mg Hydrochlorthiazide……25mg
	Diary No. Date of R& I & fee	Dy No. 9309: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensive
	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.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved
	Me-too status	Exforge HCT 5/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69549
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1201.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amlodip-H Tablet 10/25/160mg
	Composition	Each film-coated tablet contains: Amlodipine as besylate…10mg Valsartan…..160mg Hydrochlorthiazide……25mg
	Diary No. Date of R& I & fee	Dy No. 9308: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensive
	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.	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	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1202.	Name and address of manufacturer / Applicant	Cunningham Pharmaceuticals (Pvt.) Ltd., Plot # 81, Sunder Industrial Estate, Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Amlodip-H Tablet 10/25/320mg
	Composition	Each film-coated tablet contains: Amlodipine as besylate…10mg Valsartan…..320mg Hydrochlorthiazide……25mg
	Diary No. Date of R& I & fee	Dy No. 9308: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antihypertensive
	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.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved
	Me-too status	Exforge HCT 10/320/25MG film coated tablets by Novatris Pharma. Reg. No. 69552
	GMP status	GMP Certificate issued on the basis of inspection dated 01.04.2019
	Remarks of the Evaluator.	•
	Decision: Approved	
1203.	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	Arize Tablets 15mg
	Composition	Each tablet contains: Aripiprazole …….15mg
	Diary No. Date of R& I & fee	Dy No. 9529: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antipsychotics
	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.	ABILIFY® (aripiprazole) Tablets. **USFDA** approved
	Me-too status	Raylify 15mg tablet. Reg. No. 66721
	GMP status	Last GMP inspection report dated 25.102.2018 declaring following **Recommendations:** As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator.	•
	Decision: Approved	
1204.	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	Lopirox Liquid 1.5%
	Composition	Contains: Ciclopirox olamine…….1.5% (w/w)
	Diary No. Date of R& I & fee	Dy No. 9334: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Stieprox 15 mg/g **Shampoo**. **HPRA** approved
	Me-too status	Cicorox liquid. Reg. No. 82286
	GMP status	Last GMP inspection report dated 25.10.2018 declaring following **Recommendations:** As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat GMP status can only be ascertained upon the start of active production, however: Keeping in view the facility inspected the firm has requisite for manufacturing of pharmaceuticals.
	Remarks of the Evaluator.	•
	Decision: Deferred for further delibration.	
1205.	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	Evocort 250mg Tablets
	Composition	Each film-coated tablet contains: Sodium fusidate……250mg
	Diary No. Date of R& I & fee	Dy No. 9544: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Steroid antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin 250 mg Tablets, film-coated. MHRA approved
	Me-too status	Pandate 250mg Tablets, film-coated. Reg. No. 81426
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Proof of approval of the section for the applied product was asked from the firm. The firm submitted approval of general section (tablet) section.
	Decision: Deferred for approval of steroid section.	
1206.	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	Sedron 150mg Tablets
	Composition	Each film-coated tablet contains: Risedronate sodium as hemi-pentahydrate……150mg
	Diary No. Date of R& I & fee	Dy No. 9544: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ACTONEL® (risedronate sodium) film-coated tablets. **USFDA** approved
	Me-too status	Udro-150mg film-coated Tablets. Reg. No. 80979
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1207.	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	Dynacin Tablets 100mg
	Composition	Each film coated tablet contains: Minocycline as Hydrochloride…….100mg
	Diary No. Date of R& I & fee	Dy No. 9541: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Tetracyclines
	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.	Minocycline 100 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Myocin 100mg Tablet. Reg. No. 82288
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1208.	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	Alendor Tablets 70mg
	Composition	Each tablet contains: Alendronate Sodium Trihydrate eq. to Alendronic Acid…….70mg
	Diary No. Date of R& I & fee	Dy No. 9541: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Bisphosphonates

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	4's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FOSAMAX® (alendronate sodium) uncoated tablets, for oral use. **USFDA** approved
	Me-too status	Osoaid Tablets 70mg. Reg. No. 79761 (does not trihydrate form)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• .
	Decision: Approved	
1209.	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	Alendor-D Tablets
	Composition	Each tablet contains: Alendronate Sodium Trihydrate eq. to Alendronic Acid….70mg Cholecalciferol……70mcg
	Diary No. Date of R& I & fee	Dy No. 9526: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Bisphosphonates, combination
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	4's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FOSAMAX® Plus D tablets. **USFDA** approved
	Me-too status	Alendix Tablets. Reg. No. 79781(does not trihydrate form)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1210.	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	Evotrol 2mg Tablets
	Composition	Each film-coated tablet contains: Tolterodine tartrate……2mg
	Diary No. Date of R& I & fee	Dy No. 9544: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	20's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Detrusitol® 2 mg film-coated tablets. **MHRA** approved
	Me-too status	Ezeecon 2mg film-coated Tablets. Reg. No. 83232
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1211.	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	Valamax 500mg Tablets
	Composition	Each film-coated tablet contains: Valacyclovir as HCl……500mg
	Diary No. Date of R& I & fee	Dy No. 9544: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's, 10's, 42's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VALTREX (valacyclovir hydrochloride) film-coated, capsule-shaped tablets. **USFDA** approved
	Me-too status	Viro Tablets 500mg. Reg. No. 43866 (does not depict film-coated)

	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1212.	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	Selgene 5mg Tablets
	Composition	Each tablet contains: Selegiline HCl……5mg
	Diary No. Date of R& I & fee	Dy No. 9548: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Monoamine oxidase B inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ELDEPRYL® (Selegiline hydrochloride) 5mg Tablets. **MHRA** approved
	Me-too status	Elesen 5mg Tablets. Reg. No. 64657
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1213.	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	Vabrilex 500mg Tablets
	Composition	Each film-coated tablet contains: Vigabatrin……500mg
	Diary No. Date of R& I & fee	Dy No. 9544: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Fatty acid derivatives
	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.	SABRIL® (vigabatrin) film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Brizga 500mg film-coated Tablet. Reg. No. 82266
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1214.	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	Fertex 50mg Tablets
	Composition	Each tablet contains: Clomifene citrate……50mg
	Diary No. Date of R& I & fee	Dy No. 9553: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Ovulation stimulants, synthetic
	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.	Clomid™ 50mg Tablets. MHRA approved
	Me-too status	Gynofen 50mg Tablet. Reg No. 53337
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Registration Board approved registration of applied 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.	
1215.	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	Solfena 10mg Tablets

	Composition	Each film-coated tablet contains: Solifenacin succinate……10mg
	Diary No. Date of R& I & fee	Dy No. 9551: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) film-coated 10mgtablets. **USFDA** approved
	Me-too status	Solfine film-coated Tablet 10mg. Reg No. 81959
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1216.	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	Solfena 5mg Tablets
	Composition	Each film-coated tablet contains: Solifenacin succinate……5mg
	Diary No. Date of R& I & fee	Dy No. 9550: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VESIcare (solifenacin succinate) film-coated 5mgtablets. **USFDA** approved
	Me-too status	Solfine film-coated Tablet 5mg. Reg No. 81958
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1217.	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	Galamin 4mg Tablets
	Composition	Each film-coated tablet contains: Galantamine as hydrobromide……4mg
	Diary No. Date of R& I & fee	Dy No. 9536: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REMINYL 4 mg film-coated tablets. **ANSM** approved
	Me-too status	Reminyl 4Mg Tablets. Reg No. 39801
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1218.	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	Galamin 8mg Tablets
	Composition	Each film-coated tablet contains: Galantamine as hydrobromide……8mg
	Diary No. Date of R& I & fee	Dy No. 9537: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's; As per SRO
	Approval status of product in	Galantamine 8 mg Film-coated Tablets. **MHRA** approved

	Reference Regulatory Authorities.	
	Me-too status	Reminyl 8mg Tablets. Reg No. 39802
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1219.	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	Lamorig 25mg Tablets
	Composition	Each tablet contains: Lamotrigine……25mg
	Diary No. Date of R& I & fee	Dy No. 9538: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamictal 25 mg tablets. **MHRA** approved
	Me-too status	Sportin 25mg Tablets. Reg No. 70344
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1220.	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	Lamorig 50mg Tablets
	Composition	Each tablet contains: Lamotrigine……50mg
	Diary No. Date of R& I & fee	Dy No. 9539: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamictal 50 mg tablets. **MHRA** approved
	Me-too status	Sportin 50mg Tablets. Reg No. 70345
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1221.	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	Lamorig 100mg Tablets
	Composition	Each tablet contains: Lamotrigine……100mg
	Diary No. Date of R& I & fee	Dy No. 9539: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamictal 100 mg tablets. **MHRA** approved
	Me-too status	Sportin 100mg Tablets. Reg No. 70346
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1222.	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	Eldon 4mg Tablets

	Composition	Each film-coated tablet contains: Ondansetron as HCl dihydrate……4mg
	Diary No. Date of R& I & fee	Dy No. 9542: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	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.	Ondansetron 4 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 4mg. Reg No. 82656
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1223.	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	Eldon 8mg Tablets
	Composition	Each film-coated tablet contains: Ondansetron as HCl dihydrate……8mg
	Diary No. Date of R& I & fee	Dy No. 9543: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	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.	Ondansetron 8 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 8mg. Reg No. 82657
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1224.	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	Alvert 8mg Tablets
	Composition	Each tablet contains: Betahistine dihydrochloride……8mg
	Diary No. Date of R& I & fee	Dy No. 9530: 14.03.2018 PKR 20,000/-: 14.03.2018
	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	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1225.	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	Alvert 16mg Tablets
	Composition	Each tablet contains: Betahistine dihydrochloride……16mg
	Diary No. Date of R& I & fee	Dy No. 9531: 14.03.2018 PKR 20,000/-: 14.03.2018
	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	Betahistine 16 mg uncoated tablets. **MHRA** approved

	Reference Regulatory Authorities.	
	Me-too status	Histogen 16mg Tablets. Reg No. 56092
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1226.	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	Alvert 24mg Tablets
	Composition	Each tablet contains: Betahistine dihydrochloride……24mg
	Diary No. Date of R& I & fee	Dy No. 9532: 14.03.2018 PKR 20,000/-: 14.03.2018
	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	Varsilla 24mg Tablet. Reg No. 76081
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1227.	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	Amisyl 50mg Tablets
	Composition	Each tablet contains: Amisulpride……50mg
	Diary No. Date of R& I & fee	Dy No. 9527: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Benzamides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOLIAN 50 amisulpride 50 mg uncoated tablet. **TGA** approved
	Me-too status	Ampisol 50mg Tablet. Reg No. 76060
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1228.	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	Amisyl 100mg Tablets
	Composition	Each tablet contains: Amisulpride……100mg
	Diary No. Date of R& I & fee	Dy No. 9528: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Benzamides
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SOLIAN 100 amisulpride 100 mg uncoated tablet. **TGA** approved
	Me-too status	Ampisol 100mg Tablet. Reg No. 76061
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1229.	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	Ropilor 2mg Tablets
	Composition	Each film-coated tablet contains: Ropinirole as HCl……2mg
	Diary No. Date of R& I & fee	Dy No. 9547: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP (ropinirole) 2mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Balans 2mg Tablet. Reg No. 50558
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1230.	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	Ropilor 1mg Tablets
	Composition	Each film-coated tablet contains: Ropinirole as HCl……1mg
	Diary No. Date of R& I & fee	Dy No. 9546: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP (ropinirole) 1mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Balans 1mg Tablet. Reg No. 50564
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1231.	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	Ropilor 0.25mg Tablets
	Composition	Each film-coated tablet contains: Ropinirole as HCl……0.25mg
	Diary No. Date of R& I & fee	Dy No. 9545: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Dopamine agonists
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	REQUIP (ropinirole) 0.25mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Balans 0.25mg Tablet. Reg No. 50557
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1232.	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	Donaz Tablets 5mg
	Composition	Each film-coated tablet contains: Donepezil HCl……5mg
	Diary No. Date of R& I & fee	Dy No. 9534: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Anticholinesterases
	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.	ARICEPT® (donepezil hydrochloride) 5mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Nepezil 5mg film-coated Tablet. Reg No. 83285
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1233.	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	Donaz Tablets 10mg
	Composition	Each film-coated tablet contains: Donepezil HCl……10mg
	Diary No. Date of R& I & fee	Dy No. 9535: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Anticholinesterases
	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.	ARICEPT® (donepezil hydrochloride) 10mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Nepezil 10mg film-coated Tablet. Reg No. 83286
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1234.	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	Volric Tablets 200mg
	Composition	Each film-coated tablet contains: Voriconazole……200mg
	Diary No. Date of R& I & fee	Dy No. 9555: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Triazole derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VFEND® (voriconazole) 200mg film-coated tablets, for oral use. **USFDA** approved
	Me-too status	Voric 200mg film-coated Tablet Reg No. 83272
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1235.	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	Zonex Tablets 40mg
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……40mg
	Diary No. Date of R& I & fee	Dy No. 9082: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM 40MG gastro-resistant tablets. **MHRA** approved
	Me-too status	Ulcez 40mg Tablet. Reg No. 76085
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1236.	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	Zonex Tablets 20mg
	Composition	Each delayed release tablet contains: Esomeprazole as magnesium trihydrate……20mg
	Diary No. Date of R& I & fee	Dy No. 9081: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM 20MG gastro-resistant tablets. **MHRA** approved
	Me-too status	Ulcez 20mg Tablet. Reg No. 76084
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1237.	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	Revlix Capsule 6mg
	Composition	Each capsule contains: Rivastigmine as hydrogen tartrate……6mg
	Diary No. Date of R& I & fee	Dy No. 9096: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EXELON® (rivastigmine tartrate) capsules, for oral use. **USFDA** approved
	Me-too status	Riveme 6mg Capsule. Reg. No. 79954
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1238.	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	Revlix Capsule 3mg
	Composition	Each capsule contains: Rivastigmine as hydrogen tartrate……3mg
	Diary No. Date of R& I & fee	Dy No. 9095: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rivastigmine 3 mg capsules. **MHRA** approved
	Me-too status	Riveme 6mg Capsule. Reg. No. 81395
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1239.	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	Revlix Capsule 1.5mg
	Composition	Each capsule contains: Rivastigmine as hydrogen tartrate……1.5mg
	Diary No. Date of R& I & fee	Dy No. 9094: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's, 60's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	Rivastigmine 3 mg capsules. **MHRA** approved
	Me-too status	Riveme 6mg Capsule. Reg. No. 81394
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Deferred for confirmation of generic and approval status of reference regulatory authorities.	
1240.	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	Sunate Capsule 50mg
	Composition	Each capsule contains: Sunitinib as malate……50mg
	Diary No. Date of R& I & fee	Dy No. 9099: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Protein kinase inhibitors
	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.	SUTENT capsules 50mg. **USFDA** approved
	Me-too status	SUTENT 50MG CAPSULE. Reg. No. 52227
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The me-too product has mentioned Sunitinib malate instead of Sunitinib as malate. • The Registration Board in its 282nd meeting decided as: "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self contained facilities and manufacturer's shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.* *b. Anti-neoplastic Drugs (L01 class)" of WHO Anatomical Therapeutic Chemical (ATC) classification (ATC) system shall be considered as reference for categorization of drugs as Cytotoxic/Antineoplastic*" • As Sunitinib falls in Class L01, therefore, dedicated or self contained facilities is required along with the provision of safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Rejected due to non-availability of approved section	
1241.	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	Sunate Capsule 25mg
	Composition	Each capsule contains: Sunitinib as malate……25mg
	Diary No. Date of R& I & fee	Dy No. 9098: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Protein kinase inhibitors
	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.	SUTENT capsules 25mg. **USFDA** approved
	Me-too status	SUTENT 25MG CAPSULE. Reg. No. 52226
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The me-too product has mentioned Sunitinib malate instead of Sunitinib as malate. • The Registration Board in its 282nd meeting decided as: "*The manufacturing of cytotoxic drug shall be carried out in a*

		dedicated or self contained facilities and manufacturer's shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs. *b. Anti-neoplastic Drugs (L01 class)" of WHO Anatomical Therapeutic Chemical (ATC) classification (ATC) system shall be considered as reference for categorization of drugs as Cytotoxic/Antineoplastic*" • As Sunitinib falls in Class L01, therefore, dedicated or self contained facilities is required along with the provision of safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Rejected due to non-availability of approved section	
1242.	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	Evogab Capsule 100mg
	Composition	Each capsule contains: Gabapentin……100mg
	Diary No. Date of R& I & fee	Dy No. 9088: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other antiepileptics
	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.	Gabapentin 100mg Capsules. **MHRA** approved
	Me-too status	Pentowan 100mg Capsule. Reg. No. 79688
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1243.	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	Evogab Capsule 300mg
	Composition	Each capsule contains: Gabapentin……300mg
	Diary No. Date of R& I & fee	Dy No. 9089: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other antiepileptics
	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.	Gabapentin 300mg Capsules. **MHRA** approved
	Me-too status	Pentowan 300mg Capsule. Reg. No. 82103
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1244.	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	Evogab Capsule 400mg
	Composition	Each capsule contains: Gabapentin……400mg
	Diary No. Date of R& I & fee	Dy No. 9090: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other antiepileptics
	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.	Gabapentin 400mg Capsules. **MHRA** approved
	Me-too status	Neogab 400mg Capsule. Reg. No. 32055
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1245.	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	Ursicol Capsule 250mg
	Composition	Each capsule contains: Ursodeoxycholic acid…….250mg
	Diary No. Date of R& I & fee	Dy No. 9310: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	URSOFALK ursodeoxycholic acid 250mg capsule blister pack. **TGA** approved
	Me-too status	Rivsa 250mg Capsule. Reg. No. 82263
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1246.	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	Ursicol Capsule 500mg
	Composition	Each capsule contains: Ursodeoxycholic acid…….500mg
	Diary No. Date of R& I & fee	Dy No. 9311: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ursochol 500 mg capsule, hard. Swedish Medical Product Agency approved
	Me-too status	Rivsa 500mg Capsule. Reg. No. 82264
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1247.	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	Zonamid Capsule 25mg
	Composition	Each capsule contains: Zonisamide…….25mg
	Diary No. Date of R& I & fee	Dy No. 9312: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other antiepileptics
	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.	ZONISAMIDE 25 mg hard capsules. **MHRA** approved
	Me-too status	Zonisa 25mg Capsule. Reg. No. 58503
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	

1248.	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	Zonamid Capsule 50mg
	Composition	Each capsule contains: Zonisamide…….50mg
	Diary No. Date of R& I & fee	Dy No. 9313: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other antiepileptics
	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.	ZONISAMIDE 50 mg hard capsules. **MHRA** approved
	Me-too status	Zonisa 50mg Capsule. Reg. No. 58504
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1249.	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	Zonamid Capsule 100mg
	Composition	Each capsule contains: Zonisamide…….100mg
	Diary No. Date of R& I & fee	Dy No. 9314: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other antiepileptics
	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.	ZONISAMIDE 100 mg hard capsules. **MHRA** approved
	Me-too status	Zonisa 100mg Capsule. Reg. No. 58505
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1250.	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	Valzip Capsule 20mg
	Composition	Each capsule contains: Ziprasidone as HCl monohydrate…….20mg
	Diary No. Date of R& I & fee	Dy No. 9315: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GEODON 20mg hard capsules. **USFDA** approved
	Me-too status	Prazip Capsule 20mg. Reg. No. 60393
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1251.	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	Valzip Capsule 40mg
	Composition	Each capsule contains: Ziprasidone as HCl monohydrate…….40mg
	Diary No. Date of R& I & fee	Dy No. 9316: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GEODON 40mg hard capsules. **USFDA** approved
	Me-too status	Prazip Capsule 40mg. Reg. No. 60404
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1252.	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	Valzip Capsule 60mg
	Composition	Each capsule contains: Ziprasidone as HCl monohydrate…….60mg
	Diary No. Date of R& I & fee	Dy No. 9317: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GEODON 60mg hard capsules. **USFDA** approved
	Me-too status	Prazip Capsule 60mg. Reg. No. 60392
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1253.	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	Valzip Capsule 80mg
	Composition	Each capsule contains: Ziprasidone as HCl monohydrate…….80mg
	Diary No. Date of R& I & fee	Dy No. 9318: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	ANTIPSYCHOTICS, Indole derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 20's, 30's; As per SRO
	Approval status of product in RRAs.	GEODON 80mg hard capsules. **USFDA** approved
	Me-too status	Prazip Capsule 80mg. Reg. No. 60391
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1254.	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	Thiox Capsule 4mg
	Composition	Each capsule contains: Thiocolchicoside…….4mg
	Diary No. Date of R& I & fee	Dy No. 9102: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg capsule. **ANSM** approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	

1255.	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	Meconic Capsule 500mcg
	Composition	Each capsule contains: Mecobalamin …….500mcg
	Diary No. Date of R& I & fee	Dy No. 9102: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	20's, 30's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Could not be confirmed**
	Me-too status	Cobamin capsules. Reg. No. 22643
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Deferred for Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.	
1256.	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	Dobica Capsule 500mg
	Composition	Each capsule contains: Calcium dobesilate monhydrate…….500mg
	Diary No. Date of R& I & fee	Dy No. 9083: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Other sclerosing agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxium ® 500 capsule**. Swissmedic** approved
	Me-too status	DOXIUM capsule 500mg. Reg. No. 23199
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1257.	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	Loperiv Capsule 2mg
	Composition	Each capsule contains: Loperamide HCl…….…….2mg
	Diary No. Date of R& I & fee	Dy No. 9092: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Antipropulsives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's, 60's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GASTRO-STOP loperamide hydrochloride 2mg capsules**. TGA** approved
	Me-too status	IMODIUM 2MG Capsule. Reg. No. 6159
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1258.	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	Anquin Tablet 400mg
	Composition	Each film-coated tablet contains: Norfloxacin…….400mg
	Diary No. Date of R& I & fee	Dy No. 9080: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Fluoroquinolones

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Norfloxacin-ratiopharm® 400 mg tablets. MHRA approved
	Me-too status	Urac 400mg film-coated Tablets. Reg. No. 64219
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1259.	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	Synflam Tablet 275mg
	Composition	Each film-coated tablet contains: Naproxen sodium…….275mg
	Diary No. Date of R& I & fee	Dy No. 9078: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	APRANAX 275 mg film-coated tablets. **ANSM** approved
	Me-too status	Calaxin Tablets. Reg. No. 74502
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1260.	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	Epilene Plus Gel
	Composition	Each gram contains: Adapalene…….1mg Benzoyl Peroxide……..25mg
	Diary No. Date of R& I & fee	Dy No. 9324: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	adapalene, combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10g, 15g, 30g, 45g, 50g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Epiduo 0.1% / 2.5% gel. MHRA approved
	Me-too status	Adoxide Gel. Reg. No. 85169
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1261.	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	Epilene Gel 0.3%
	Composition	Each gram contains: Adapalene…….3mg
	Diary No. Date of R& I & fee	Dy No. 9323: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10g, 15g, 30g, 45g, 50g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Differin® 0.3% gel. **USFDA** approved
	Me-too status	Adapco Forte Gel. Reg. No. 83213
	GMP status	As recorded for above application

	Remarks of the Evaluator.	•
	Decision: Approved	
1262.	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	Epilene Gel 0.1%
	Composition	Each gram contains: Adapalene…….1mg
	Diary No. Date of R& I & fee	Dy No. 9322: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10g, 15g, 30g, 45g, 50g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Differin® 0.1% gel. **USFDA** approved
	Me-too status	Semycin Gel. Reg. No. 78623
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1263.	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	Epilene Cream 0.1%
	Composition	Each gram contains: Adapalene…….1mg
	Diary No. Date of R& I & fee	Dy No. 9321: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10g, 15g, 30g, 45g, 50g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Differin 0.1% Cream. **MHRA** approved
	Me-too status	Adapal Cream 0.1%. Reg. No. 83838
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1264.	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	Evonex Cream 0.005%
	Composition	Each gram contains: Calcipotriol as monohydrate…….0.05mg
	Diary No. Date of R& I & fee	Dy No. 9326: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other antipsoriatics for topical use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Calcipotriol Cream 50 micrograms/g. **MHRA** approved
	Me-too status	Calcipot Cream Reg. No. 69823
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1265.	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	Evonex Ointment 0.005%
	Composition	Each gram contains: Calcipotriol…….....0.05mg

	Diary No. Date of R& I & fee	Dy No. 9327: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other antipsoriatics for topical use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	15g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DAIVONEX calcipotriol 50 micrograms/g ointment tube. **TGA** approved
	Me-too status	Sfonex Ointment. Reg. No. 85170
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1266.	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	Silevo Cream 1%
	Composition	Each gram contains: Silver sulfadiazine…….10mg
	Diary No. Date of R& I & fee	Dy No. 9330: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Sulfonamides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10g, 20g, 250g, 500g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Flamazine Cream 1.0%w/w. **MHRA** approved
	Me-too status	SILZIN CREAM Reg. No. 21193
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1267.	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	Klotriz Cream 1%
	Composition	Each gram contains: Clotrimazole…….10mg
	Diary No. Date of R& I & fee	Dy No. 9329: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Imidazole and triazole derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10g, 15g, 20g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clotrimazole 1% Cream. **MHRA** approved
	Me-too status	DERMOSPORIN (SKIN) CRM Reg. No. 8505
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1268.	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	Femcin-V (vaginal) Cream 2%
	Composition	Each gram contains: Clindamycin as phosphate…….20mg
	Diary No. Date of R& I & fee	Dy No. 9328: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	40g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dalacin Cream 2%. **MHRA** approved
	Me-too status	Abwo Vaginal Cream 2% Reg. No. 82547

	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1269.	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	Acneza Cream 20%
	Composition	Each gram contains: Azelaic acid…….200mg
	Diary No. Date of R& I & fee	Dy No. 9325: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Other anti-acne preparations for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5g, 10g, 15g, 20, 25g, 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Skinoren 20% Cream. **MHRA** approved
	Me-too status	Skinex Cream Reg. No. 84452
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1270.	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	Vabrilex Sachet 500mg
	Composition	Each Sachet contains: Vigabatrin…….500mg
	Diary No. Date of R& I & fee	Dy No. 9333: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	ANTIEPILEPTICS, Fatty acid derivatives
	Type of Form	Form 5
	Finished Product Specification	Available in USP as " for solution"
	Pack size & Demanded Price	10's, 20's, 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sabril® 500 mg granules for oral solution. **MHRA** approved (granular powder)
	Me-too status	Vlep 500mg Sachet Reg. No. 70474
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The me-too product does not clarify whether the content is granules or powder. • The USP has used the term powder in the assay procedure and did not mention dissolution test thereof.
	Decision: Deferred for clarification from the firm.	
1271.	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	Vofen Sachet 600mg
	Composition	Each sachet contains: Ibuprofen…….600mg
	Diary No. Date of R& I & fee	Dy No. 9332: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Brufen® 600mg Effervescent Granules. **MHRA** approved
	Me-too status	Brufen 600mg Sachet Reg. No. 44414
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The me-too product does not clarify whether the content is granules or powder.
	Decision: Deferred for clarification.	

1272.	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	Volric Dry suspension 200mg/5ml
	Composition	Each 5ml (after reconstitution) contains: Voriconazole…….200mg
	Diary No. Date of R& I & fee	Dy No. 9331: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Triazole derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	60ml, 75ml, 90ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Voriconazole Pfizer 40 mg/ml powder for oral suspension. **MHRA** approved
	Me-too status	Voric 200mg/5ml Suspension. No. 83917
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The me-too data does not clarify whether the product is suspension or 'powder for suspension'.
	Decision: Deferred for clarification.	
1273.	Name and address of manufacturer / Applicant	McOLSON Research Laboratories (Pvt.) Ltd 26th Km. Lahore-Sharikpur Road Distt. Sheikhupura
	Brand Name +Dosage Form + Strength	Racitam 250mg tablet
	Composition	Each film-coated tablet contains: Levetiracetam….250mg
	Diary No. Date of R& I & fee	Dy No. 9770: 15.03.2018 PKR 20,000/-: 14.03.2018
	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.	Levetiracetam 250 mg film-coated tablets. MHRA approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	"Last GMP inspection report dated 15-02-2018 declaring following " General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure."
	Remarks of the Evaluator.	•
	Decision: Approved	
1274.	Name and address of manufacturer / Applicant	McOLSON Research Laboratories (Pvt.) Ltd 26th Km. Lahore-Sharikpur Road Distt. Sheikhupura
	Brand Name +Dosage Form + Strength	Racitam 500mg tablet
	Composition	Each film-coated tablet contains: Levetiracetam….500mg
	Diary No. Date of R& I & fee	Dy No. 9769: 15.03.2018 PKR 20,000/-: 14.03.2018
	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.	Levetiracetam 500 mg film-coated tablets. MHRA approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	As recorded for above application

	Remarks of the Evaluator.	•
	Decision: Approved	
1275.	Name and address of manufacturer / Applicant	McOLSON Research Laboratories (Pvt.) Ltd 26th Km. Lahore-Sharikpur Road Distt. Sheikhupura
	Brand Name +Dosage Form + Strength	M-Gab 75mg Capsule
	Composition	Each capsule contains: Pregabalin….75mg
	Diary No. Date of R& I & fee	Dy No. 9768: 15.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 75 mg Capsules, Hard. MHRA approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1276.	Name and address of manufacturer / Applicant	McOLSON Research Laboratories (Pvt.) Ltd 26th Km. Lahore-Sharikpur Road Distt. Sheikhupura
	Brand Name +Dosage Form + Strength	McProx 20mg Tablet
	Composition	Each film-coated contains: Paroxetine as HCl hemihydrate….20mg
	Diary No. Date of R& I & fee	Dy No. 9771: 15.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	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.	Paroxetine 20 mg Film-coated tablets. MHRA approved
	Me-too status	Frais Tablet 20mg. Reg. No. 82658 (Does not depict hemihydrate)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Firm revised Paroxetine as HCl to Paroxetine as HCl hemihydrate
	Decision: Approved	
1277.	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	Usodex 250mg Capsule
	Composition	Each capsule contains: Ursodeoxycholic acid…250mg
	Diary No. Date of R& I & fee	Dy No. 15210: 24.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Bile acids and derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	URSOFALK ursodeoxycholic acid 250mg capsule blister pack. **TGA** approved
	Me-too status	Rivsa 250mg Capsule. Reg. No. 82263
	GMP status	The firm was inspected on 07.09.2017, wherein the following Observations/ Recommendations were made: "1- Improve quality assurance system as per GMP GUIDELINES. 2- Develop annual product review system for marketed products. Overall the firm was working under satisfactory level of GMP."
	Remarks of the Evaluator.	•
	Decision: Approved	

1278.	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	Dia-Farm 50mg Capsule
	Composition	Each capsule contains: Diacerein…50mg
	Diary No. Date of R& I & fee	Dy No. 15210: 24.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, non-steroids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	ART 50 mg capsule. **ANSM** approved
	Me-too status	Diora 50mg Capsule. Reg. No. 67631
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1279.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi
	Brand Name +Dosage Form + Strength	Torfen 100mg/5ml Liquid Suspension
	Composition	Each 5ml contains: Ibuprofen…100mg
	Diary No. Date of R& I & fee	Dy No. 15520: 26.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 120ml; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Proven oral suspension ibuprofen 20mg/mL oral liquid bottle. TGA approved
	Me-too status	Azofin Suspension. Reg. No. 20860
	GMP status	The firm was inspected on 05.10.2017, with the following conclusion; "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 the Evaluator.	•
	Decision: Approved	
1280.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; contract manufacturing by: Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	SEC 40mg IV Injection
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 9513: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate. The firm M/s Honig Pharmaceuticals was inspected on 11.10.2018 and reported complying GMP.

	Remarks of the Evaluator.	• The shelf-life of the product in TGA is 18 months. • The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • Adjustment of weight of API as per salt factor is required in Master Formula. • The firm has mentioned the dosage form as injection. However, the composition and manufacturing outlines depict that the product is lyophilized powder for injection. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer. • The firm was asked to clarify the lyophilization process, but the firm did not reply.
	Decision: Deferred for the following: • **Adjustment of weight of API as per salt factor is required in Master Formula.** • **Clarify whether the product is filled and lyophilized or only lyophilized powder is filled.** • **Clarify the dosage form.**	
1281.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; contract manufacturing by: Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Moxing 400mg/250ml IV Injection
	Composition	Each 250ml contains: Moxifloxacin as HCl……400mg
	Diary No. Date of R& I & fee	Dy No. 9512: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	(250ml) 1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	AVELOX IV 400 moxifloxacin 400 mg/250 mL (as hydrochloride) intravenous infusion solution bottle. TGA approved
	Me-too status	Esobrain Injection 40mg. Reg. No. 85072
	GMP status	
	Remarks of the Evaluator.	• The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • The firm mentioned HDPE as primary packaging. Then changed to LDPE). The reference product is packed in Glass Type I clear bottle. • The firm was asked for adjustment of weight of API as per salt factor. The firm did not revised the same. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer.
	Decision: Deferred for clarification about the packaging.	

1282.	Name and address of manufacturer / Applicant	M/s Honig Pharmaceuticals Labs. – Rawalpindi 14 KM, Adyala Road, Rawalpindi; contract manufacturing by: Vision Pharmaceuticals Plot # 22-23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Xamp 40mg IV Injection
	Composition	Each vial contains: Esomeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 9511: 14.03.2018 PKR 50,000/-: 14.03.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	NEXIUM IV esomeprazole 40mg (as sodium) powder for injection vial. TGA approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	
	Remarks of the Evaluator.	• The firm M/s Honig Pharmaceuticals has submitted inspection report for DML renewal, wherein 04 sections have been mentioned. • The firm M/s Honig Pharmaceuticals has submitted a list of 09 approved product for contact manufacturing. • The firm M/s Honig Pharmaceuticals has submitted a list of 03 products applied for contact manufacturing by M/s Honig Pharmaceuticals. • The firm has mentioned the dosage form as injection. However, the composition and manufacturing outlines depict that the product is lyophilized powder for injection. • The firm has provided copy of contract manufacturing agreement between the applicant and manufacturer. • Adjustment of weight of API as per salt factor is required in Master Formula. • The firm has mentioned 33% potency of lyophilized powder, but did not clarify the other 67% composition. • The firm was asked to clarify the lyophilization process, but the firm did not reply.
	Decision: Decision: Deferred for the following: • **Adjustment of weight of API as per salt factor is required in Master Formula.** • **Clarification whether the product is filled and lyophilized or only lyophilized powder is filled.** • **Clarification of the dosage form.** • **Clarification about the composition of the dosage form (powder).**	
1283.	Name and address of manufacturer / Applicant	Navegal Laboratories 41/1-A2, Phase-1, Industrial Estate Hattar
	Brand Name +Dosage Form + Strength	Oslu 75mg Capsule
	Composition	Each capsule contains: Oseltamivir as phosphate…..75mg
	Diary No. Date of R& I & fee	Dy No. 39117: 28.11.2018 PKR 20,000/-: 28.11.2018
	Pharmacological Group	Neuraminidase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's, 2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TAMIFLU® (oseltamivir phosphate) capsules, for oral use. USFDA approved
	Me-too status	Tamiflu 75Mg Capsules. Reg. No. 39619
	GMP status	The firm was inspecvted on 31.12.2016, wherein renewal of DML was recommended.

	Remarks of the Evaluator.	•
	Decision: Deferred for consideration on its its turn.	
1284.	Name and address of manufacturer / Applicant	Navegal Laboratories 41/1-A2, Phase-1, Industrial Estate Hattar
	Brand Name +Dosage Form + Strength	Cinapar 90mg Tablet
	Composition	Each film-coated tablet contains: Cinacalcet as HCl…..90mg
	Diary No. Date of R& I & fee	Dy No. 38725: 26.11.2018 PKR 20,000/-: 26.11.2018
	Pharmacological Group	Other anti-parathyroid agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1x10's, 1x15's, 2x10's, 2x15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cinacalcet 90 mg film-coated tablets. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspecvted on 31.12.2016, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	•
	Decision: Deferred for submission of stability studies.	
1285.	Name and address of manufacturer / Applicant	Navegal Laboratories 41/1-A2, Phase-1, Industrial Estate Hattar
	Brand Name +Dosage Form + Strength	Cinapar 60mg Tablet
	Composition	Each film-coated tablet contains: Cinacalcet as HCl…..60mg
	Diary No. Date of R& I & fee	Dy No. 38724: 26.11.2018 PKR 20,000/-: 26.11.2018
	Pharmacological Group	Other anti-parathyroid agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1x10's, 1x15's, 2x10's, 2x15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cinacalcet 60 mg film-coated tablets. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspecvted on 31.12.2016, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	•
	Decision: Deferred for submission of stability studies.	
1286.	Name and address of manufacturer / Applicant	Navegal Laboratories 41/1-A2, Phase-1, Industrial Estate Hattar
	Brand Name +Dosage Form + Strength	Cinapar 30mg Tablet
	Composition	Each film-coated tablet contains: Cinacalcet as HCl…..30mg
	Diary No. Date of R& I & fee	Dy No. 38723: 26.11.2018 PKR 20,000/-: 26.11.2018
	Pharmacological Group	Other anti-parathyroid agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1x10's, 1x15's, 2x10's, 2x15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cinacalcet 30 mg film-coated tablets. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspecvted on 31.12.2016, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	•
	Decision: Deferred for submission of stability studies.	
1287.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial

		Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Menem Powder for solution for injection 500mg
	Composition	Each vial contains: Meropenemas as trihydrate……500mg
	Diary No. Date of R& I & fee	Dy No. 9524: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MERREM® IV (meropenem for injection) 500mg, for intravenous use. US-FDA approved
	Me-too status	Engpan Injection 500mg. Reg. No. 64555
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, firm revised it to Powder for solution for injection.
	Decision: Deferred for the following: • **List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required.** • **List of product applied for contact manufacturing by M/s Winthrox Laboratories is required.** • **List of all approved sections of M/s Winthrox Laboratories is required.**	
1288.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Menem Powder for solution for injection 1g
	Composition	Each vial contains: Meropenem as trihydrate……1g
	Diary No. Date of R& I & fee	Dy No. 9523: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MERREM® IV (meropenem for injection) 1g, for intravenous use. US-FDA approved
	Me-too status	Meropeon Injection 1g. Reg. No. 78145
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm revised it to Powder for solution for injection.
	Decision: Deferred for the following: • **List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required.** • **List of product applied for contact manufacturing by M/s Winthrox Laboratories is required.** • **List of all approved sections of M/s Winthrox Laboratories is required.**	

1289.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tazowin Powder for solution for injection 4.5g
	Composition	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium……0.5g
	Diary No. Date of R& I & fee	Dy No. 9523: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Piperacillin and beta-lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for injection, for intravenous use. US-FDA approved
	Me-too status	Tanzo Injection. Reg. No. 39439
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, firm now revised it to Powder for solution for injection
	Decision: Deferred for the following: • **List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required.** • **List of product applied for contact manufacturing by M/s Winthrox Laboratories is required.** • **List of all approved sections of M/s Winthrox Laboratories is required.**	
1290.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tazowin Powder for solution for injection 2.25g
	Composition	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium……0.25g
	Diary No. Date of R& I & fee	Dy No. 9521: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Piperacillin and beta-lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for injection, for intravenous use. USFDA approved
	Me-too status	Tanzo Injection. Reg. No. 39593
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Tazowin 2.5 has been mentioned on fee challan instead of Tazowin 2.25 • List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However,

		the firm revised it to Powder for solution for injection.
	Decision: Deferred for the following: • **Submission of undertaking about the fee challan.** • **List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required.** • **List of product applied for contact manufacturing by M/s Winthrox Laboratories is required.** • **List of all approved sections of M/s Winthrox Laboratories is required.**	
1291.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Imicil Powder for solution for injection
	Composition	Each vial contains: Imipenem as monohydrate…..500mg Cilastin as sodium…….500mg
	Diary No. Date of R& I & fee	Dy No. 9520: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	PRIMAXIN® (imipenem and cilastatin) for Injection, for intravenous use. USFDA approved
	Me-too status	Imclas Injection IV. Reg. No. 48341
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm revised it to Powder for solution for injection.
	Decision: Deferred for the following: • **List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required.** • **List of product applied for contact manufacturing by M/s Winthrox Laboratories is required.** • **List of all approved sections of M/s Winthrox Laboratories is required.**	
1292.	Name and address of manufacturer / Applicant	Genetics Pharmaceuticals (Pvt.) Limited., 539-A, Sunder Industrial Estate Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Entrate 70mg Tablet
	Composition	Each tablet contains: Alendronate Sodium Trihydrate eq. to Alendronic Acid….70mg
	Diary No. Date of R& I & fee	Dy No. 9772: 15.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Bisphosphonates
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	4's, 10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	FOSAMAX® (alendronate sodium) uncoated tablets, for oral use. USFDA approved
	Me-too status	Osoaid Tablets 70mg. Reg. No. 79761 (does not trihydrate form)
	GMP status	The firm was inspected on 29.03.2019, wherein the panel concluded that the firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	•
	Decision: Approved	

1293.	Name and address of manufacturer / Applicant	Genetics Pharmaceuticals (Pvt.) Limited., 539-A, Sunder Industrial Estate Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Revalp 250mg ER Tablet
	Composition	Each extended release tablet contains: Divalproex sodium eq. to Valproic acid……250mg
	Diary No. Date of R& I & fee	Dy No. 9773: 15.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's, 50's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Depakote® ER Divalproex sodium extended-release 250mg tablets. USFDA approved with box warning
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 29.03.2019, wherein the panel concluded that the firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• Adjust weight of API in Master Formula as per salt factor. • Proof of approval of me-too product with same dosage form, strength and salt form by DRAP is required.
	Decision: Deferred for the following: • **Adjustment of weight of API in Master Formula as per salt factor.** • **Proof of approval of me-too product with same dosage form, strength and salt form by DRAP is required.**	
1294.	Name and address of manufacturer / Applicant	Genetics Pharmaceuticals (Pvt.) Limited., 539-A, Sunder Industrial Estate Raiwand Road Lahore
	Brand Name +Dosage Form + Strength	Revalp 500mg ER Tablet
	Composition	Each extended release tablet contains: Divalproex sodium eq. to Valproic acid……500mg
	Diary No. Date of R& I & fee	Dy No. 9774: 15.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30's, 50's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Depakote® ER Divalproex sodium extended-release 500mg tablets. USFDA approved with box warning
	Me-too status	Volpar CR 500mg Tablets. Reg. No. 73237
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1295.	Name and address of manufacturer / Applicant	Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Flueze DS Expectorant (flavored liquid)
	Composition	Each 20ml contain: Acetaminophen…..650mg Phenylephrine……10mg Dextromethorphan HBr…….20mg Guaifenesin……400mg
	Diary No. Date of R& I & fee	Dy No. 9029: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Analgesic + decongestant + cough suppressant + expectorasnt (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed

	GMP status	The firm was inspected on 09.11.2018, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	Facility for water processing with details is required.
	Decision: Deferred for the following: • **Proof of approval of me-too product with same dosage form, strength and salt form by DRAP.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.** • **Facility for water processing with details.**	
1296.	Name and address of manufacturer / Applicant	Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Flueze Plus Expectorant (flavored liquid)
	Composition	Each 10ml contain: Dextromethorphan HBr…….20mg Guaifenesin……200mg
	Diary No. Date of R& I & fee	Dy No. 9030: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	dextromethorphan, combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 09.11.2018, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	Facility for water processing with details is required.
	Decision: Deferred for the following: • **Proof of approval of me-too product with same dosage form, strength and salt form by DRAP.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.** • **Facility for water processing with details.**	
1297.	Name and address of manufacturer / Applicant	Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Flueze Plus cough syrup
	Composition	Each 20ml contain: Dextromethorphan HBr…….30mg Doxylamine Succinate…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 9032: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	dextromethorphan, combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 09.11.2018, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	• Facility for water processing with details is required.
	Decision: Deferred for the following: • **Proof of approval of me-too product with same dosage form, strength and salt form by DRAP.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.** • **Facility for water processing with details.**	
1298.	Name and address of manufacturer / Applicant	Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Flueze cough syrup
	Composition	Each 5ml contain:

		Dextromethorphan HBr…….30mg
	Diary No. Date of R& I & fee	Dy No. 9031: 12.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	dextromethorphan, combinations
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 09.11.2018, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	• Facility for water processing with details is required.
	Decision: Deferred for the following: • **Proof of approval of me-too product with same dosage form, strength and salt form by DRAP.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.** • **Facility for water processing with details.**	
1299.	Name and address of manufacturer / Applicant	Zafa Pharmaceutical Laboratories (Private) Limited A-46, SITE North Karachi
	Brand Name +Dosage Form + Strength	Dydrone Tablet 10mg
	Composition	Each film-coated tablet contains: Dydrogesterone…….10mg
	Diary No. Date of R& I & fee	Dy No. 9283: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Duphaston 10 mg film-coated tablets. Approved in Belgium
	Me-too status	D-Gest 10mg Tablets. Reg. No. 77100
	GMP status	The firm was inspected on 07.02.2019, wherein the GMP was rated as GOOD
	Remarks of the Evaluator.	• The firm submitted that they will use trans-isomer of API.
	Decision: Deferred for confirmation of approval of the section.	
1300.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd., Plot # 549, Sundar Industrial Estate, Raiwand Road, Lahore
	Brand Name +Dosage Form + Strength	Trexate 2.5mg Tablet
	Composition	Each tablet contains: Methotrexate……..2.5mg
	Diary No. Date of R& I & fee	Dy No. 39220: 29.11.2018 PKR 20,000/-: 28.11.2018
	Pharmacological Group	Other immunosuppressants (L04AX03)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Maxtrex 2.5 mg un-coated tablets. MHRA approved
	Me-too status	METHOTREXATE TABLET 2.5MG. Reg. No. 66007
	GMP status	The firm has been issued DML on the basis of inspection dated 13.07.2017 and 04.10.2017.
	Remarks of the Evaluator.	• The Registration Board in its 282nd meeting decided as: "*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self contained facilities and manufacturer's shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.*

		b. Anti-neoplastic Drugs (L01 class)" of WHO Anatomical Therapeutic Chemical (ATC) classification (ATC) system shall be considered as reference for categorization of drugs as Cytotoxic/Antineoplastic" • As methotrexate also falls in Class L01, therefore, dedicated or self contained facilities is required along with the provision of safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Approved with innovator's specifications	
1301.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd., Plot # 549, Sundar Industrial Estate, Raiwand Road, Lahore
	Brand Name +Dosage Form + Strength	Trexate 10mg Tablet
	Composition	Each tablet contains: Methotrexate……..10mg
	Diary No. Date of R& I & fee	Dy No. 39220: 29.11.2018 PKR 20,000/-: 28.11.2018
	Pharmacological Group	Other immunosuppressants (L04AX03)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's, 50's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Maxtrex 10 mg un-coated tablets. MHRA approved
	Me-too status	METHOTREXATE TABLET 10MG. Reg. No. 66009
	GMP status	The firm has been issued DML on the basis of inspection dated 13.07.2017 and 04.10.2017.
	Remarks of the Evaluator.	"*The manufacturing of cytotoxic drug shall be carried out in a dedicated or self contained facilities and manufacturer's shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.* *b. Anti-neoplastic Drugs (L01 class)" of WHO Anatomical Therapeutic Chemical (ATC) classification (ATC) system shall be considered as reference for categorization of drugs as Cytotoxic/Antineoplastic*" • As methotrexate also falls in Class L01 , therefore, dedicated or self contained facilities is required along with the provision of safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	Decision: Approved with innovator's specifications	
1302.	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	Terbiwrd 250mg Tablet
	Composition	Each uncoated tablet contains: Terbinafine as HCL…250mg
	Diary No. Date of R& I & fee	Dy No. 15369: 25.04.2018 PKR 20,000/-: 04.04.2018
	Pharmacological Group	Antifungals for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 250mg (as hydrochloride) tablet, uncoated. **TGA** approved
	Me-too status	Terbin DS Tablets 250mg. Reg. No. 49235
	GMP status	Inspection was conducted on 12.11.2018, wherein the following sections of the firm were considered to be operating at satisfactory level of GMP.

		i) Tablet Section (General/antibiotics) ii) Liquid injectable section (General/antibiotics) iii) Dry injectable section (General/antibiotics) iv) Dry powder injectable (cephalosporins) 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.	•
	Decision: Approved	
1303.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Simcol 40mg Oral Drops
	Composition	Each ml Contains: Simethicone…40mg
	Diary No. Date of R& I & fee	Dy No. 14972: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Antiflatulent
	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.	Infacol 40mg/ml oral drops (suspension). MHRA approved
	Me-too status	Minicol Drops. Reg. No. 36627
	GMP status	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved	
1304.	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	Athrocin DS
	Composition	Each 5ml contains: Azithromycin as dihydrate……200mg
	Diary No. Date of R& I & fee	Dy No. 9296: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	15ml, 25ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 200 mg/5 ml Suspension. **MHRA** approved
	Me-too status	Chemzee Dry Powder Suspension. Reg. No. 35875
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	• The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. The firm was asked for provision of the same. The firm did not respond. • The firm has mentioned the dosage form as suspension instead of dry suspension in Form 5.
	Decision: Deferred for provision of provision of Amperometric electrochemical detector with Dual glassy carbon Electrode	
1305.	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	AMLO 2.5mg Tablet
	Composition	Each tablet contains: Amlodipine as besylate……2.5mg
	Diary No. Date of R& I & fee	Dy No. 9297: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	NORVASC® (amlodipine besylate) 2.5mg Tablets for oral administration. **USFDA** approved
	Me-too status	Amlocard 2.5 Tablets Reg. No. 20554
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	
	Decision: Approved	
1306	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	AMLO 5mg Tablet
	Composition	Each tablet contains: Amlodipine as besylate……5mg
	Diary No. Date of R& I & fee	Dy No. 9298: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	NORVASC® (amlodipine besylate) 5mg Tablets for oral administration. **USFDA** approved
	Me-too status	Amlocard 5 Tablets Reg. No. 20555
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	•
	Decision: Approved	
1307	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	AMLO 10mg Tablet
	Composition	Each tablet contains: Amlodipine as besylate……10mg
	Diary No. Date of R& I & fee	Dy No. 9299: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Dihydropyridine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	NORVASC® (amlodipine besylate) 10mg Tablets for oral administration. **USFDA** approved
	Me-too status	Amlocard 10 Tablets Reg. No. 20556
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	
	Decision: Approved	
1308	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	Athrocin 250mg Tablet
	Composition	Each film-coated tablet contains: Azithromycin as dihydrate ……250mg
	Diary No. Date of R& I & fee	Dy No. 9293: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX (azithromycin) 250 mg film-coated tablet. **USFDA** approved
	Me-too status	Macrocap film-coated 250mg Tablets. Reg. No. 84260

	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	
	Decision: Approved	
1309	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	Athrocin 500mg Tablet
	Composition	Each film-coated tablet contains: Azithromycin as dihydrate……500mg
	Diary No. Date of R& I & fee	Dy No. 9294: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX (azithromycin) 500 mg film-coated tablet. **USFDA** approved
	Me-too status	Macrocap film-coated 500mg Tablets. Reg. No. 84261
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	
	Decision: Approved	
1310	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	Athrocin 100mg/5ml Dry Suspension
	Composition	Each 5ml contains: Azithromycin as dihydrate ……100mg
	Diary No. Date of R& I & fee	Dy No. 9294: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	15ml, 25ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX (azithromycin) 100mg/5ml suspension. **USFDA** approved
	Me-too status	Azitma 100mg/5ml Suspension. Reg. No. 74901
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	• The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. The firm was asked for provision of the same. The firm did not respond. • The firm has mentioned the dosage form as suspension instead of dry suspension in Form 5.
	Decision: Approved	
1311	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	Drotaspin 40mg Tablet
	Composition	Each tablet contains: Drotaverine HCl ……40mg
	Diary No. Date of R& I & fee	Dy No. 9294: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Papaverine and derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm ahs claimed in-house specifications
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Apporved in three EMA states as un-coated tablets in Hungary (both coated and uncoated), Romania & Solvakia (both coated and uncoated).
	Me-too status	Spasmostar Tablets. Reg. No. 78711

	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	The firm was asked to provide complete finished product specifications in line with General chapters of pharmacopeia (list of tests, reference to analytical procedures, and proposed acceptance criteria). Firm submitted incomplete specifications.
	Decision: Approved with innovator's specifications.	
1312	Name and address of manufacturer / Applicant	Global Pharmaceuticals Plot # 204-205, Industrial triangle, Kahuta Road, Islamabad; Contract manufacturing by Vision Pharmaceuticals Plot #22-23, Industrial triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Neuro Vita 3ml Injection
	Composition	Each 03 ml ampoule contains: Thiamine chloride HCl …..100mg Pyridoxine HCl ….100mg Vitamin B12…..1000mcg
	Diary No. Date of R& I & fee	Dy No. 2448: 18.01.2018 PKR 20,000/-: 18.01.2018 PKR 30,000/-: 18.04.2019
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	3ml x 25's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Neurobion® solution for injection. **DIMDI Germany** approved
	Me-too status	NEUROBION INJ. Reg. No. 1485
	GMP status	The firm M/s Vision Pharma was inspected on 11.02.2019, wherein issuance of GMP certificate was recommended. The firm M/s Global Pharma was inspected on 11. & 24.10.2018, wherein issuance of GMP certificate was recommended.
	Remarks of the Evaluator.	• Fee of Rs. 20,000 has been submitted by Vision Pharmaceuticals. While fee of Rs. 30000/- has been submitted by Global Pharma. • In the agreement, it has been mentioned that the agreement is signed in the presence of witnesses. However, names and signatures (thumb impressions) of witnesses are not present thereof. • First page of Form 5 shall be signed M/s Global Pharmaceuticals. • The firm has revised thiamine to thiamine chloride HCl without submission of fee. • The firm has revised to pyridoxine to pyridoxine HCl without submission of fee.
	Decision: Registration Board decided to refer the case to Division of Legal Affairs (DRAP) for clarification of the following: • **Fee of Rs. 20,000 has been submitted by Vision Pharmaceuticals. While fee of Rs. 30000/- has been submitted by Global Pharma.** • **In the agreement, it has been mentioned that the agreement is signed in the presence of witnesses. However, names and signatures (thumb impressions) of witnesses are not present thereof.** • **The firm has revised thiamine to thiamine chloride HCl without submission of fee.** • **The firm has revised to pyridoxine to pyridoxine HCl without submission of fee.**	
1313	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Dotril 10mg Sachet
	Composition	Each sachet contains: Racecadotril…..10mg

	Diary No. Date of R& I & fee	Dy No. 15146: 24.04.2018 PKR 50,000 +10,000/-: 23.04.2018 (For Dotril 10mg Sachet + Dotril 30mg Sachet + Dotril 100mg Capsule)
	Pharmacological Group	Other antidiarrheals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	16's; Rs. 875
	Approval status of product in Reference Regulatory Authorities.	TIORFAN 10 mg INFANTS, oral powder in sachet-dose. ANSM Approved HIDRASEC INFANTS 10 mg, Granules for oral suspension. MHRA approved (the pharmaceutical form is Granules for oral suspension White powder with characteristic apricot smell)
	Me-too status	Could not be confirmed
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	•
	Decision: Deferred for submission of stability studies.	
1314	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Dotril 30mg Sachet
	Composition	Each sachet contains: Racecadotril…30mg
	Diary No. Date of R& I & fee	Dy No. 15146: 24.04.2018 PKR 50,000 +10,000/-: 23.04.2018 (For Dotril 10mg Sachet + Dotril 30mg Sachet + Dotril 100mg Capsule)
	Pharmacological Group	Other antidiarrheals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	16's; Rs. 875 (to avoid confusion; same as for 10mg)
	Approval status of product in Reference Regulatory Authorities.	TIORFAN 30 mg CHILDREN, oral powder in sachet-dose. ANSM Approved HIDRASEC CHILDREN 30 mg, Granules for oral suspension. MHRA approved (the pharmaceutical form is Granules for oral suspension White powder with characteristic apricot smell)
	Me-too status	Could not be confirmed
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	• Provide complete finished product specifications in line with general chapters (list of tests, reference to analytical procedures, and proposed acceptance criteria), including tests for granules.
	Decision: Deferred for submission of stability studies.	
1315	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Dotril 100mg capsule
	Composition	Each capsule contains: Racecadotril…100mg
	Diary No. Date of R& I & fee	Dy No. 15147: 24.04.2018 PKR 50,000 +10,000/-: 23.04.2018 (For Dotril 10mg Sachet + Dotril 30mg Sachet + Dotril 100mg Capsule)
	Pharmacological Group	Other antidiarrheals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; Rs. 654
	Approval status of product in Reference Regulatory Authorities.	HIDRASEC 100 mg hard capsules. MHRa approved
	Me-too status	Could not be confirmed
	GMP status	GMP granted on the basis of inspection dated 16.10.2018

	Remarks of the Evaluator.	•
	Decision: Deferred for submission of stability studies.	
1316	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Emerep 40mg Capsule
	Composition	Each Capsule Contains: Aprepitant…40mg
	Diary No. Date of R& I & fee	Dy No. 15151: 24.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Other antiemetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's; Rs. 2545.52/-
	Approval status of product in Reference Regulatory Authorities.	EMEND (aprepitant) 40mg capsules, for oral use. USFDA approved.
	Me-too status	Apreon 40mg Capsules. Reg. No. 68201
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	•
	Decision:	
1317	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Emerep 80mg Capsule
	Composition	Each Capsule Contains: Aprepitant…80mg
	Diary No. Date of R& I & fee	Dy No. 15152: 24.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Other antiemetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	6's; Rs.7967.24/-
	Approval status of product in Reference Regulatory Authorities.	EMEND (aprepitant) 80mg capsules, for oral use. USFDA approved.
	Me-too status	Apreon 80mg Capsules. Reg. No. 68202
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	•
	Decision: Approved	
1318	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Emerep 125mg Capsule
	Composition	Each Capsule Contains: Aprepitant…125mg
	Diary No. Date of R& I & fee	Dy No. 15150: 24.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Other antiemetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's; Rs. 2545.52/-
	Approval status of product in Reference Regulatory Authorities.	EMEND (aprepitant) 125mg capsules, for oral use. USFDA approved.
	Me-too status	Apreon 125mg Capsules. Reg. No. 68203
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	•
	Decision: Approved	
1319	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Choir 1mg/ml Oral Solution
	Composition	Each ml contains: Risperidone…1mg
	Diary No. Date of R& I & fee	Dy No. 15145: 24.04.2018 PKR 20,000/-: 23.04.2018

	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml; Rs. 189/-
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL® (risperidone) oral solution. USFDA approved.
	Me-too status	Apreon 125mg Capsules. Reg. No. 68203
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	•
	Decision: Approved	
1320	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Res-Med 2mg Tablet
	Composition	Each tablet Contains: Risperidone.....…2mg
	Diary No. Date of R& I & fee	Dy. No. 15537: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Other antipsychotics
	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.	RISPERDAL® (risperidone) 2mg tablets, for oral use. USFDA approved
	Me-too status	Rislet 2mg Tablet. Reg. No. 76412
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator.	The firm had provided international availability of film-coated tablet, but did not mention label claim and coating composition in Master Formula. However, coating process is present in manufacturing outlines. Upon clarification, the firm revised all the required documents to film-coated tablet with submission of Rs.5,000/- fee.
	Decision: Approved.	
1321	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Res-Med 1mg Tablet
	Composition	Each tablet Contains: Risperidone…1mg
	Diary No. Date of R& I & fee	Dy No. 15536: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Other antipsychotics
	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.	RISPERDAL® (risperidone) 1mg tablets, for oral use. **USFDA** approved
	Me-too status	Rislet 1mg Tablet. Reg. No. 76417
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm had provided international availability of film-coated tablet, but did not mention label claim and coating composition in Master Formula. However, coating process is present in manufacturing outlines. Upon clarification, the firm revised all the required documents to film-coated tablet with submission of Rs.5,000/- fee.
	Decision: Approved.	

1322	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Megrital 400mg Tablet
	Composition	Each tablet contains: Carbamazepine…..400mg
	Diary No. Date of R& I & fee	Dy No. 15536: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Antiepileptics
	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.	Could not be confirmed
	Me-too status	Tegral 400mg Tablet. Reg. No. 79918 (does not depict coating)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Clarification is required about solvent-E. • The firm revised the formulation from coated tablet to un-caoted tablet with submission of Rs. 5000/- fee.
	Decision: Deferred for clarification about solvent-E.	
1323	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Topage 50mg Tablet
	Composition	Each film-coated tablet contains: Topiramate …..50mg
	Diary No. Date of R& I & fee	Dy No. 15541: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Other antiepileptics
	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.	Topamax® 50 mg film-coated tablets. **MHRA** approved
	Me-too status	Topister Tablet 50mg. Reg. No. 82548
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1324	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent (Water for Injection) 10ml Type I glass
	Composition	Each ampule contains: Sterile water for Injection …..10ml
	Diary No. Date of R& I & fee	Dy No. 15540: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Solvents and diluting agents, incl. irrigating solutions
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml, As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	STERILE WATER FOR INJECTION 100% (10ml) in vial. **USFDA** approved
	Me-too status	Water for Injection (sterile) 10ml in ampule. Reg. No. 76972
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1325	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent (Water for Injection) 2ml Type I glass
	Composition	Each ampule contains: Sterile water for Injection …..2ml
	Diary No. Date of R& I & fee	Dy No. 15538: 26.04.2018 PKR 20,000/-: 26.04.2018

	Pharmacological Group	Solvents and diluting agents, incl. irrigating solutions
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2ml, As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Water for Injections BP (sterile injection) 2ml ampule. MHRA approved
	Me-too status	Water for Injection (sterile) 2ml (ampule). Reg. No. 76466
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1326	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent (Water for Injection) 3ml Type I glass
	Composition	Each ampule contains: Sterile water for Injection …..3ml
	Diary No. Date of R& I & fee	Dy No. 15539: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Solvents and diluting agents, incl. irrigating solutions
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	3ml, As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Water for Injections BP 5ml. **MHRA** approved. Could not be confirmed in the applied volume, i.e., 3ml
	Me-too status	Water for Injection (sterile) 3ml (ampule). Reg. No. 76465
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1327	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent 5 ml (Type I glass ampule) for Medisonate Injection
	Composition	Each 5ml ampule contains: Sodium chloride…..0.9%
	Diary No. Date of R& I & fee	Dy No. 15539: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5ml, As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Sodium Chloride 0.9% w/v Injection BP 5 ml in hermitically sealed translucent plastic ampule. **MHRA** approved.
	Me-too status	Water for Injection (sterile) 3ml (ampule). Reg. No. 76465
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm mentioned sodium hydroxide and HCl for pH adjustment in manufacturing outlines. However, these are not present in Master formula. The firm was asked for justification in line with the reference product. The firm did not reply.
	Decision: Deferred for further clarification/revision of formulation.	
1328	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent 1 ml (Type I glass ampule) for Medisonate Injection
	Composition	Each 1ml ampule contains: Sodium bicarbonate…..5%
	Diary No. Date of R& I & fee	Dy No. 15534: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form 5
	Finished Product Specification	???
	Pack size & Demanded Price	1ml, As per DRAP Policy
	Approval status of product in	Could not be confirmed

	Reference Regulatory Authorities.	
	Me-too status	Sodium Bicarbonate Injection. Reg. No. 76428 (does not specify the pack volume)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has mentioned sodium hydroxide and HCl for pH adjustment in manufacturing outlines. However, these are not present in Master formula. Justification in line with the reference product is required. • Complete finished product specifications in line with general chapters of pharmacopeia (list of tests, reference to analytical procedures, and proposed acceptance criteria) are required.
	Decision: Deferred for the following. • **Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.** • **Complete finished product specifications in line with general chapters of pharmacopeia (list of tests, reference to analytical procedures, and proposed acceptance criteria) are required.**	
1329.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract munafacturing by: M/s Daneen Pharma (Pvt) Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore.
	Brand Name +Dosage Form + Strength	Cariclor 125mg/5ml Powder for Oral Solution
	Composition	After reconstitution each 5ml contain: Cefaclor Monohydrate Eq. to Cefaclor…125mg
	Diary No. Date of R& I & fee	Dy No. 15529: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Distaclor 125mg/5ml Granule for Suspension. **MHRA** approved
	Me-too status	Eclor Oral Suspension 125mg/5ml Dry Suspension. R.#083946
	GMP status	The firm M/s Genix Pharma was inspected on 16.02.2018, with the following conclusion: "In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other cGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an satisfactory level of compliance with cGMP guidelines as of today. The management was also suggested to further strengthen stability and analytical sections. The firm M/s Genix Pharma has submitted inspection report of M/s King Pharmaceutical 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan dated 06.02.2018, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section. • The firm has applied for "powder for suspension". However, the firm has mentioned granulation process and upon clarification, provided evidence of reference product "granule for suspension"
	Decision: Approved.	

1330.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract munafacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cariclor 250mg/5ml Powder for Oral Solution
	Composition	After reconstitution each 5ml contain: Cefaclor Monohydrate Eq. to Cefaclor…250mg
	Diary No. Date of R& I & fee	Dy No. 15530: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Distaclor 250mg/5ml granule for Suspension. **MHRA** approved
	Me-too status	Eclor Oral Suspension 250mg/5ml Dry Suspension. Reg. No. 83945
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section. • The firm has applied for "powder for suspension". However, the firm has mentioned granulation process and upon clarification, provided evidence of reference product "granule for suspension".
	Decision: Approved	
1331.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract munafacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore.
	Brand Name +Dosage Form + Strength	Cariclor 500mg Capsule
	Composition	Each Capsule Contains: Cefaclor Monohydrate Eq. to Cefaclor…500mg
	Diary No. Date of R& I & fee	Dy No. 15532: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefaclor Capsules 500mg (Cefaclor monohydrate Ph Eur Eq. to 500mg of Cefaclor). Approved by MHRA
	Me-too status	Deduclol 500mg Capsule. Reg. No. 80639
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1332.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract munafacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore.
	Brand Name +Dosage Form + Strength	Cariclor 250mg Capsule

	Composition	Each Capsule Contains: Cefaclor Monohydrate Eq. to Cefaclor…250mg
	Diary No. Date of R& I & fee	Dy No. 15531: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	7's, 10's, 14's, 21's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefaclor Capsules 250mg (Cefaclor monohydrate Ph Eur Eq. to 250mg of Cefaclor). Approved by MHRA
	Me-too status	Deduclol 250mg Capsule. Reg. No. 80640
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1333.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract munafacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore.
	Brand Name +Dosage Form + Strength	Keprex 250mg Powder for Injection
	Composition	Each Vial Contains: Cefotaxime Sodium Eq. to Cefotaxime…250mg
	Diary No. Date of R& I & fee	Dy No. 15522: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CEFOTAXIMA NORMON 250 mg POWDER AND SOLVENT FOR SOLUTION INJECTABLE IV EFG. CIMA approved
	Me-too status	Varxiame 250mg IM/IV Injection. Reg. No. 49270
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1334.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract manufacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Keprex 1g Powder for Injection
	Composition	Each Vial Contains: Cefotaxime Sodium Eq. to Cefotaxime…1g
	Diary No. Date of R& I & fee	Dy No. 15524: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CEFOTAXIME INJECTION cefotaxime 1g (as sodium) powder for injection IV. TGA approved
	Me-too status	Varxiame 500mg IM/IV Injection. Reg. No. 49272

	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1335.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract manufacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore.
	Brand Name +Dosage Form + Strength	Keprex 500mg Powder for Injection
	Composition	Each Vial Contains: Cefotaxime Sodium Eq. to Cefotaxime…500mg
	Diary No. Date of R& I & fee	Dy No. 15523: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefotaxime 500 mg powder for solution for injection. MHRA approved
	Me-too status	Varxiame 500mg IM/IV Injection. Reg. No. 49271
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1336.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract manufacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Xytol 2g Powder for Injection
	Composition	Each vial contains: Cefoperazone Sodium Eq. to Cefoperazone…1g Sulbactam Sodium Eq. to Sulbactam…1g
	Diary No. Date of R& I & fee	Dy No. 15528: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	1's, 10's; 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	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	

1337.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract manufacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore.
	Brand Name +Dosage Form + Strength	Xytol 1g Powder for Injection
	Composition	Each vial contains: Cefoperazone Sodium Eq. to Cefoperazone…500mg Sulbactam Sodium Eq. to Sulbactam…500mg
	Diary No. Date of R& I & fee	Dy No. 15527: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection. PMDA Approved
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section..
	Decision: Approved	
1338.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract manufacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Aleeva 500mg Powder for Injection
	Composition	Each vial contains: Cefepime as HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 15525: 26.04.2018 PKR 50,000/-: 25.04.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use. USFDA Approved
	Me-too status	Cefevial Injection 500 mg IV Reg. No. 80029
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1339.	Name and address of manufacturer / Applicant	M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan. Contract manufacturing by: M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Raod, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Aleeva 1g Powder for Injection
	Composition	Each vial contains: Cefepime as HCl…1g
	Diary No. Date of R& I & fee	Dy No. 15526: 26.04.2018 PKR 50,000/-: 25.04.2018

	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use. USFDA Approved
	Me-too status	Cefevial Injection 1g IV Reg. No. 80030
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm M/s Genix Pharma has submitted list of 11 products approved for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 17 products applied for contract manufacturing. • The firm M/s Genix Pharma has submitted list of 04 approved section.
	Decision: Approved	
1340.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Myosone Tablet 50mg
	Composition	Each film-coated tablet contains: Eperisone hydrochloride…50mg
	Diary No. Date of R& I & fee	Dy No. 15771: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	30's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Expose 50mg film coated tablet. **AIFA** approved
	Me-too status	Soma 50 mg Tablets film-coated. Reg. No. 78470
	GMP status	The firm was inspected on 17.01.2019 with the following recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator.	• The firm has provided facility of water processing without specifications. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Approved	
1341.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Coxlab Tablet 60mg
	Composition	Each film-coated tablet contains: Etoricoxib…….60mg
	Diary No. Date of R& I & fee	Dy No. 15774: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 30's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	ARCOXIA etoricoxib 60mg film-coated tablet. **TGA** approved
	Me-too status	Gencox 60mg Tablets film-coated. Reg. No. 78839
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Approved	
1342.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	MBC 135mg Tablets
	Composition	Each film-coated tablet contains: Mebeverine HCl…135mg
	Diary No. Date of R& I & fee	Dy No. 15783: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	30's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	COLESE mebeverine hydrochloride 135mg tablet film-coated. **TGA** approved
	Me-too status	Mebofac Tablets 135mg film-coated. Reg. No. 74267
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Approved	
1343.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Flovas 4mg Tablet
	Composition	Each film-coated tablet contains: Pitavstatin Calcium eq. to Pitavastatin…4mg
	Diary No. Date of R& I & fee	Dy No. 15783: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	JP (with label claim: Pitavastatin Calcium Tablets contain not less than 95.0% and not more than 105.0% of the labeled amount of pitavastatin calcium)
	Pack size & Demanded Price	30's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	LIVALO (pitavastatin) Tablet, Film Coated for Oral use. **USFDA** approved
	Me-too status	Astin 4mg Tablet. Reg. No. 70449
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs.20,000/- fee dated 31.01.2019.
	Decision: Approved	
1344.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Ranx 500mg Tablet
	Composition	Each film-coated extended release tablet contains: Ranolazine…500mg
	Diary No. Date of R& I & fee	Dy No. 15779: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 30's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	RANEXA® (ranolazine) 500mg extended-release tablets, film-coated. **USFDA** approved
	Me-too status	Rangizin XR Tablet. Reg. No. 76770
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised the formulation from film-coated to film coated, extended release tablet (in line with the reference product) along with submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Approved	
1345.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Ranx 1000mg Tablet
	Composition	Each film-coated tablet contains: Ranolazine…1000mg
	Diary No. Date of R& I & fee	Dy No. 15780: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	????
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	RANEXA® (ranolazine) 1000mg extended-release tablets, film-coated. **USFDA** approved
	Me-too status	Ranzol-XR 1000mg Tablet. Reg. No. 61010
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised the formulation from film-coated to film coated, extended release tablet (in line with the reference product) along with submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for clarification of finished product specifications.	
1346.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nicoran 20mg Tablet
	Composition	Each tablet contains: Nicorandil…20mg
	Diary No. Date of R& I & fee	Dy No. 15786: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	IKOREL Nicorandil 20mg tablet un-coated. **TGA** approved
	Me-too status	Nicogina 20mg Tablet. Reg. No. 67050
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised the label claim to un-coated tablet with submission of Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for submission of complete manufacturing outlines.	
1347.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nicoran 10mg Tablet

	Composition	Each tablet contains: Nicorandil…10mg
	Diary No. Date of R& I & fee	Dy No. 15785: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	IKOREL Nicorandil 10mg tablet un-coated. **TGA** approved
	Me-too status	Nicogina 10mg Tablet. Reg. No. 67049
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised the label claim to un-coated tablet with submission of Rs. 5000/- fee. • Undertaking at the end of revised form is missing. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for submission of complete manufacturing outlines.	
1348.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 90mg Tablet
	Composition	Each film-coated, extended release tablet contains: Diltiazem HCl…90mg
	Diary No. Date of R& I & fee	Dy No. 15795: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	Available in USP as extended release
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CARDIZEM® 90mg tablet un-coated. **USFDA** approved
	Me-too status	Could not be confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised the label claim to exztended release tablet with submission of Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for Submission of complete manufacturing outlines.	
1349.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 120mg Tablet
	Composition	Each film-coated, extended release tablet contains: Diltiazem HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 15796: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	Available in USP as extended release
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CARDIZEM® 120mg tablet un-coated. **USFDA** approved
	Me-too status	Could not be confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised the label claim to exztended release tablet with submission of Rs. 5000/- fee.

		• Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for submission of complete manufacturing outlines.	
1350.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Liptin-M 50/500mg Tablet
	Composition	Each film-coated tablet contains: Sitagliptin as phophpahte monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 15787: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 30'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	As recorded for above application
	Remarks of the Evaluator.	• The firm revised Sitagliptin to Sitagliptin as phophpahte monohydrate (Form 5, master Formula, weight adjustment as per slat factor) in line with the reference product along with submission Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for Submission of complete manufacturing outlines.	
1351.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Liptin-M 50/1000mg Tablet
	Composition	Each film-coated tablet contains: Sitagliptin…50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15788: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 30'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	As recorded for above application
	Remarks of the Evaluator.	• The firm revised Sitagliptin to Sitagliptin as phophpahte monohydrate (Form 5, master Formula, weight adjustment as per slat factor) in line with the reference product along with submission Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for Submission of complete manufacturing outlines.	
1352.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 90mg Capsule

	Composition	Each capsule contains: Diltiazem HCl (as sustained release pellets)…90mg
	Diary No. Date of R& I & fee	Dy No. 15797: 27.04.2018 PKR 20,000/-: 27.04.2018 PKR 5,000/-: 29.04.2019
	Pharmacological Group	Other vasodilators used in cardiac diseases
	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.	Angitil SR 90mg MR capsules. **MHRA** approved
	Me-too status	TIAZEM SR 90MG CAP. Reg No. 10863
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has revised formulation in line with the reference product without submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019. • The pellets have been tested /analysed with unknown specifications. • The long term stability of pellets has been conducted at 25±2 C, 65±5 RH. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Decision: Deferred for the following: • **The reference for specifications of pellets.** • **The long term stability of pellets shall be conducted in zone IV-A.** • **Differential fee for imported pellets is required.** • **GMP certificate of source of pellets is required.**	
1353.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 180mg Capsule
	Composition	Each capsule contains: Diltiazem HCl (as sustained release pellets)…180mg
	Diary No. Date of R& I & fee	Dy No. 15798: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	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.	Angitil SR 180mg MR capsules. MHRA approved
	Me-too status	Could not be confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has revised formulation in line with the reference product without submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No.33 Sundar Industrial Estate, Lahore and submitted Rs.20,000/- fee dated 31.01.2019. • The pellets have been tested /analysed with unknown specifications. • The long term stability of pellets has been conducted at 25±2 C, 65±5 RH. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Decision: Deferred for the following: • **The reference for specifications of pellets.** • **The long term stability of pellets shall be conducted in zone IV-A.**	

	• **Differential fee for imported pellets is required.** **GMP certificate of source of pellets is required.**	
1354.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Clowin 50mg tablet
	Composition	Each tablet contains: Clomiphene citrate…50mg
	Diary No. Date of R& I & fee	Dy No. 15781: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	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.	GENRX CLOMIPHENE clomifene citrate 50mg tablet, un-coated. **TGA** approved
	Me-too status	OVA-MIT TABLETS. Reg. No. 20404
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Blistering and packing steps are missing in the manufacturing outlines. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for submission of complete manufacturing outlines.	
1355.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Clowin 50mg capsule
	Composition	Each capsule contains: Clomiphene citrate…50mg
	Diary No. Date of R& I & fee	Dy No. 15782: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	PROLIFEN CAP. Reg. No. 10250
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Blistering and packing steps are missing in the manufacturing outlines. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Decision: Deferred for the following: • **Submission of complete manufacturing outlines.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board**	
1356.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Prostem 400mcg capsule
	Composition	Each capsule contains: Tamsulosin HCl (modified release pellets)…400mcg
	Diary No. Date of R& I & fee	Dy No. 15776: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Drugs used in benign prostatic hypertrophy
	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	FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral

	Reference Regulatory Authorities.	use. **USFDA** approved
	Me-too status	Tamsolin 0.4mg Capsule. Reg. No. 50392
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 18.01.2019. • Blistering and packing steps are missing in the manufacturing outlines. • The firm has revised the salt form of API and formulation in line with the reference product with submission of Rs. 5000/- fee. • The pellets have been tested with in-house specifications. • The long term stability of pellets has been conducted at 25±2 C, 65±5 RH. • Differential fee for imported pellets is required.
	Decision: Deferred for the following: • **Submission of complete manufacturing outline.** • **The long term stability of pellets shall be conducted in zone IV-A.** • **Differential fee for imported pellets is required.** • **GMP certificate of source of pellets is required.**	
1357.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jmslim 120mg capsule
	Composition	Each capsule contains: Orlistat…120mg
	Diary No. Date of R& I & fee	Dy No. 15775: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Beacita 120mg Capsules, hard. **MHRA** approved
	Me-too status	Xenical Capsule. Reg. No. 42142
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Diltiazem HCl has been mentioned in the filling step of manufacturing outlines • Blistering and packing steps are missing in the manufacturing outlines.
	Decision: Deferred for submission of complete manufacturing outlines.	
1358.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Clarip Tablet 500mg
	Composition	Each film-coated tablet contains: Clarithromycin…..500mg
	Diary No. Date of R& I & fee	Dy No. 14987: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Macrolides
	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.	Clarithromycin 500 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Clarital 500mg Tablet. Reg. No. 85500
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection,

		areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form 5 is missing.
	Decision: Deferred for submission of First page of Form 5.	
1359.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Clarip Tablet 250mg
	Composition	Each film-coated tablet contains: Clarithromycin…..250mg
	Diary No. Date of R& I & fee	Dy No. 14986: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Macrolides
	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.	Clarithromycin 250 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Clarital 250mg Tablet. Reg. No. 85501
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form 5 is missing.
	Decision: Deferred for submission of First page of Form 5.	
1360.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	J-Artan Tablet 25mg
	Composition	Each film-coated tablet contains: Losartan Potassium…..25mg
	Diary No. Date of R& I & fee	Dy No. 14990: 23.04.2018 PKR 20,000/-: 23.04.2018
	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.	Cozaar® 25 mg film-coated tablets. **MHRA** approved
	Me-too status	Lotass 25mg Tablet. Reg. No. 66802
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Firm submitted updated Form 5. First page of Form 5 is missing.
	Decision: Deferred for submission of First page of Form 5.	
1361.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	J-Artan Tablet 50mg
	Composition	Each film-coated tablet contains: Losartan Potassium…..50mg
	Diary No. Date of R& I & fee	Dy No. 14991: 23.04.2018 PKR 20,000/-: 23.04.2018
	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.	Cozaar® 50 mg film-coated tablets. **MHRA** approved
	Me-too status	Lotass 50mg Tablet. Reg. No. 66803
	GMP status	As recorded for above application
	Remarks of the Evaluator.	Firm submitted updated Form 5. First page of Form 5 is missing.
	Decision: Deferred for submission of First page of Form 5.	

1362.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Clarip Dry Suspension 250mg/5ml
	Composition	Each 5ml contain: Clarithromycin…..250mg
	Diary No. Date of R& I & fee	Dy No. 14984: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Macrolides
	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.	Clarithromycin 250mg/5ml granules for oral suspension. **MHRA** approved
	Me-too status	KETEK 250 mg/5ml Oral Suspension. Reg. No. 84173 (does not depict granules)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form 5 is missing.
	Decision: Deferred for submission of First page of Form 5.	
1363.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Truvan-D 80+12.5mg Tablets
	Composition	Each film-coated tablet contains: Valsartan…….80mg Hydrochlorthiazide…..12.5mg
	Diary No. Date of R& I & fee	Dy No. 26932: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensives
	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.	Co-Diovan 80mg/12.5mg film-coated tablets by Novartis Farma S.p.A., Via Provinciale Schito. Approved by **MHRA**
	Me-too status	Valzar Plus 80/12.5 Tablets by Remington Pharmaceuticals (Pvt) Ltd,. Reg. No. 50901
	GMP status	The firm has been granted GMP inspection on the basis of inspection dated 24.12.2018.
	Remarks of the Evaluator.	•
	Decision: Approved	
1364.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Truvan-D 160+25mg Tablets
	Composition	Each film-coated tablet contains: Valsartan USP…….160mg Hydrochlorthiazide BP…..25mg
	Diary No. Date of R& I & fee	Dy No. 26934: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensives
	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.	Co-Diovan 160mg/25mg film-coated tablets by Novartis Farma S.p.A., Via Provinciale Schito. Approved by **MHRA**
	Me-too status	Valzar Plus 160/25 Tablets by Remington Pharmaceuticals (Pvt) Ltd. Reg. No. 50900
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	

1365.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Truvan-D 160+12.5mg Tablets
	Composition	Each film-coated tablet contains: Valsartan USP…….160mg Hydrochlorthiazide BP…..12.5mg
	Diary No. Date of R& I & fee	Dy No. 26933: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensives
	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.	Co-Diovan 160mg/12.5mg tablets by Novartis Farma S.p.A., Via Provinciale Schito. Approved by **MHRA**
	Me-too status	Velker Plus Tablet by High-Q Pharma Karachi.. Reg. No. 76210
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1366.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Saipin F 6/25 mg Capsules
	Composition	Each capsule contains: Olanzapine…….6mg Fluoxetine as HCl…..25mg
	Diary No. Date of R& I & fee	Dy No. 26932: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specs (Available in USP)
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Co-Depricap 6/25 Capsule by NabiQasim Karachi. Reg. No. 76135
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised Fluoxetine to Fluoxetine (as hydrochloride) without submission of any fee.
	Decision: approved with USP specifications.	
1367.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Saipin F 6/50 mg Capsules
	Composition	Each capsule contains: Olanzapine…….6mg Fluoxetine as HCl…..50mg
	Diary No. Date of R& I & fee	Dy No. 26938: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specs (Available in USP)
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Not confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm revised Fluoxetine to Fluoxetine (as hydrochloride) without submission of any fee.
	Decision: Deferred for submission of fee for revision of formulation	
1368.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Saipin F 12/50mg Capsules

	Composition	Each capsule contains: Olanzapine…….12mg Fluoxetine as HCl…..50mg
	Diary No. Date of R& I & fee	Dy No. 26939: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specs (Available in USP)
	Pack size & Demanded Price	2x7; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Not confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm revised Fluoxetine to Fluoxetine (as hydrochloride) without submission of any fee.
	Decision: Deferred for submission of fee for revision of formulation	
1369.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Saipin F 3/25mg Capsules
	Composition	Each capsule contains: Olanzapine…….3mg Fluoxetine as HCl…..25mg
	Diary No. Date of R& I & fee	Dy No. 26935: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specs (Available in USP)
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Dipof 3/25 mg capsule by Global Pharmaceuticals. Reg. No. 77899
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm revised Fluoxetine to Fluoxetine (as hydrochloride) without submission of any fee.
	Decision: Deferred for submission of fee for revision of formulation	
1370.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Saipin F 12/25mg Capsules
	Composition	Each capsule contains: Olanzapine…….12mg Fluoxetine as HCl…..25mg
	Diary No. Date of R& I & fee	Dy No. 26937: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specs (Available in USP)
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Amprexa-F 12/25mg Capsule by Amarant Pharma (R.#076751)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm revised Fluoxetine to Fluoxetine (as hydrochloride) without submission of any fee.
	Decision: Deferred for submission of fee for revision of formulation	
1371.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Truvan 160mg Tablets
	Composition	Each film-coated tablet contains: Valsartan……..160mg

	Diary No. Date of R& I & fee	Dy No. 26931: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	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.	Cuenca 160 mg film-coated tablets by Laboratorios Liconsa, S.A. Approved by **MHRA**
	Me-too status	Velker Tablet by High-Q Pharma Karachi. Reg. No. 76209
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1372.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Truvan 80mg Tablets
	Composition	Each film-coated tablet contains: Valsartan……..80mg
	Diary No. Date of R& I & fee	Dy No. 26931: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	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.	Cuenca 00 mg film-coated tablets by Laboratorios Liconsa, S.A. Approved by **MHRA**
	Me-too status	Velker 80 mg Tablet by High-Q Pharma Karachi. Reg. No. 76202
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1373.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norvan HCT 5+80+12.5mg Tablets
	Composition	Each film-coated tablet contains: Amlodipine as besilate (BP)…..5mg Valsartan (USP)……..80mg Hydrochlorthiazide (BP)….12.5mg
	Diary No. Date of R& I & fee	Dy No. 26941: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for the following: • **Proof of approval of me-too product with same dosage form, same strength and same pack size by DRAP.** • **Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.**	
1374.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norvan HCT 5+160+25mg Tablets
	Composition	Each film-coated tablet contains: Amlodipine as besilate (BP)…..5mg Valsartan (USP)……..160mg Hydrochlorthiazide (BP)….25mg

	Diary No. Date of R& I & fee	Dy No. 26942: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x14'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 5/160/25MG film coated tablets by Novatris Pharma. Reg. No. 69549
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1375.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norvan HCT 5+160+12.5mg Tablets
	Composition	Each film-coated tablet contains: Amlodipine as besilate (BP).....5mg Valsartan (USP).....160mg Hydrochlorthiazide (BP)....12.5mg
	Diary No. Date of R& I & fee	Dy No. 26940: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x14'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 5/160/12.5MG film coated tablets by Novatris Pharma. Reg. No. 69548
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1376.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norvan HCT 10+160+25mg Tablets
	Composition	Each film-coated tablet contains: Amlodipine as besilate (BP).....10mg Valsartan (USP).....160mg Hydrochlorthiazide (BP)....25mg
	Diary No. Date of R& I & fee	Dy No. 26944: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x14'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	As recorded for above application
	Remarks of the Evaluator.	Correction of quantity of Hydrochlorthiazide in Master Formula is required.
	Decision: Deferred for correction of quantity of Hydrochlorthiazide in Master Formula.	
1377.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norvan HCT 10+160+12.5mg Tablets
	Composition	Each film-coated tablet contains: Amlodipine as besilate (BP).....10mg

		Valsartan (USP)……..160mg Hydrochlorthiazide (BP)….12.5mg
	Diary No. Date of R& I & fee	Dy No. 26943: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x14'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 10/160/12.5MG film coated tablets by Novatris Pharma. Reg. No. 69550
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1378.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Spasnil Tablets
	Composition	Each tablet contains: Phloroglucinol…..80mg trimethylphloroglucinol ……..80mg
	Diary No. Date of R& I & fee	Dy No. 26908: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PHLOROGLUCINOL / TRIMETHYLPHLOROGLUCINOL ACINO 62.233 mg / 80 mg, coated tablet by ACINO France SAS. Approved by **ANSM**
	Me-too status	Despasm Tablet by Irza Pharmaceuticals. Reg. No. 85210
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• International availability is the form of sugar-coated tablet. The firm revised the formulation to sugar-coated tablet without submission of prescribed fee and correction of label. Morever, sugar/sucrose has not been mentioned in the composition of coating • The API 'Phloroglucinol' is the form of 'Phloroglucinol hydrate'. Necessary correction is required.
	Decision: Deferred for the following: • **Submission of fee for revision of formulation.** • **Correction of label and composition of coating** • **Correction of'Phloroglucinol' to 'Phloroglucinol hydrate'.**	
1379.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Trupride 1mg Tablet
	Composition	Each tablet contains: Cinitapride hydrogen tartarate eq. to Cinitapride …..1mg
	Diary No. Date of R& I & fee	Dy No. 26907: 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 has claimed innovator's specifications.
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Blaston 1 mg Tablets by LACER, SA. Approved by Spanish Agency of Medicines and Health Products
	Me-too status	Cint 1mg Tablet by High-Q Pharmaceuticals. Reg. No. 73888
	GMP status	As recorded for above application

	Remarks of the Evaluator.	• Mention correct quantity of API in Master Formula after adjustment of salt factor.
	Decision: Deferred for correction of quantity of API in Master Formula.	
1380.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bera 20mcg Tablet
	Composition	Each film-coated tablet contains: Beraprost as sodium …..20mcg
	Diary No. Date of R& I & fee	Dy No. 26906: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Benprost 20mcg tablet by Nabiqasim Karachi. Reg. No. 61237
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1381.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Impat 100mg Tablet
	Composition	Each film-coated tablet contains: Lacosamide …..100mg
	Diary No. Date of R& I & fee	Dy No. 26911: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm did not mentioned in reference
	Pack size & Demanded Price	1x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire 100 mg film-coated tablets by Aspire Pharma Limited. **MHRA** Approved
	Me-too status	Lalap 100mg Tablet by Genix Pharma (Pvt.) Ltd. Reg. No. 70471
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1382.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Impat 50mg Tablet
	Composition	Each film-coated tablet contains: Lacosamide …..50mg
	Diary No. Date of R& I & fee	Dy No. 26910: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm did not mentioned in reference
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire 50 mg film-coated tablets by Aspire Pharma Limited. **MHRA** Approved
	Me-too status	Lalap 50mg Tablet by Genix Pharma (Pvt.) Ltd. Reg. No. 70470
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1383.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	TIO-F Capsule
	Composition	Each capsule contains: Tiotropium (as bromide monohydrate)…..18mcg

		Formoterol fumarate dihydrate…….12mcg
	Diary No. Date of R& I & fee	Dy No. 26904: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Innovator's specifications.
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Tiovair-F Rotacaps by Highnoon Laboratories. Reg. No. 054314
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board is required. • Provision of manufacturing facility for steroid-based rotacap is required.
	Decision: deferred for the following: • **Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.** • **Provision of manufacturing facility for steroid-based rotacap.**	
1384.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bufor Capsule
	Composition	Each capsule contains: Budenoside…..200mcg Formoterol fumarate as dihydrate…….6mcg
	Diary No. Date of R& I & fee	Dy No. 26909: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	3×10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Provision of manufacturing facility for steroid-based rotacap is required. • Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board is required. • The registration Board in its 283rd meeting approved Wilsonide Plus 200mcg+6mcg Rotacaps of M/s Wilson's Pharmaceuticals on the basis of Symbicort 200/6 Turbohaler, Inhalation Powder by M/s AstraZeneca (MHRA Approved) with the following decision "*Registration Board deliberated that instant product is in unit dose preparation / rotacap having same dose per actuation as in multidose product. Thus Registration Board approved the product."*
	Decision: Deferred for the following: • **Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.** • **Provision of manufacturing facility for steroid-based rotacap.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1385.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Etor Tablet 60mg

	Composition	Each film-coated tablet contains: Etoricoxib…..60mg
	Diary No. Date of R& I & fee	Dy No. 26903: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Anti-inflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA 60 mg film-coated tablets by Merck Sharp & Dohme BV. **ANSM** approved
	Me-too status	Eto 60 mg Tablet by Linta Pharmaceuticals. Reg No. 78176
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision: Approved	
1386.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Ronic Tablet 150mg
	Composition	Each film-coated tablet contains: Ibandronate sodium monohydrate eq. to ibnadronic acid …..150mg
	Diary No. Date of R& I & fee	Dy No. 26903: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Drugs affecting bone structure and mineralization
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	BONIVA (ibandronate sodium) film-coated Tablets by Hoffmann LA Roche. **US-FDA** approved
	Me-too status	Ibadron 150mg Tablet by S.J.&G.FazulEllahie(Pvt) Ltd. Reg No. 58637
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The firm revised the salt form ibandronate sodium as monohydrate eq. to ibnadronic acid 150mg without submission of any fee.
	Decision: Deferred for submission of fee for revision of formulation.	
1387.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bosent Tablet 62.5mg
	Composition	Each film-coated tablet contains: Bosentan as monohydrate…..62.5mg
	Diary No. Date of R& I & fee	Dy No. 26914: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensives for pulmonary arterial hypertension
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRACLEER® (bosentan) film-coated tablets, for oral use by Actelion Pharms Ltd. **US-FDA** approved
	Me-too status	Bosecard 62.5mg tablet by Zafa Pharma Karachi. Reg No. 81464
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1388.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bosent Tablet 125mg
	Composition	Each film-coated tablet contains: Bosentan as monohydrate…..125mg
	Diary No. Date of R& I & fee	Dy No. 26915: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antihypertensives for pulmonary arterial hypertension
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.

	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRACLEER® (bosentan) film-coated tablets, for oral use by Actelion Pharms Ltd. **US-FDA** approved
	Me-too status	Bozpah 125mg Tablet by Nabiqasim Karachi. Reg No. 81521
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1389.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Dechol Tablet 40mg
	Composition	Each film-coated tablet contains: Atorvastatin (as calcium trihydrate).....40mg
	Diary No. Date of R& I & fee	Dy No. 26926: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	HMG CoA reductase 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.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Fatilor 40mg Tablet by Lisko Pakistan Ltd. Reg No. 58163 (does not depict film-coating)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1390.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Dechol Tablet 20mg
	Composition	Each film-coated tablet contains: Atorvastatin (as Atorvastatin calcium trihydrate).....20mg
	Diary No. Date of R& I & fee	Dy No. 26925: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	HMG CoA reductase 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.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Torvia 20mg Tablet by Pakistan Pharmaceutical Products. Reg No. 81161
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1391.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Dechol Tablet 10mg
	Composition	Each film-coated tablet contains: Atorvastatin (as Atorvastatin calcium trihydrate).....10mg
	Diary No. Date of R& I & fee	Dy No. 26924: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	HMG CoA 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.	ACH-ATORVASTATIN CALCIUM (film-coated) by Accord Healthcare Inc. **Health Canada** approved
	Me-too status	Torvia 10mg Tablet by Pakistan Pharmaceutical Products. Reg. No. 81162
	GMP status	As recorded for above application

	Remarks of the Evaluator.	•
	Decision: Approved	
1392.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Linezolid Tablet 600mg
	Composition	Each film-coated tablet contains: Linezolid…..600mg
	Diary No. Date of R& I & fee	Dy No. 26921: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	3x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) 600mg tablets (film-coated) for oral use by Pharmacia and Upjohn. **US-FDA** approved
	Me-too status	Ozlin 600 mg Tablet by Linta Pharmaceuticals. Reg No. 78179
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1393.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Linezolid Tablet 400mg
	Composition	Each film-coated tablet contains: Linezolid…..400mg
	Diary No. Date of R& I & fee	Dy No. 26920: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Antibacterials for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	3x4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) tablets (film-coated) for oral use by Pharmacia and Upjohn. not discontinued or withdrawn by US-FDA for safety or efficacy reasons
	Me-too status	Enliv 400mg Tablet by PharmEvo (Pvt.) Ltd. Reg No. 58096 (does not depict coating)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1394.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bystol Tablet 10mg
	Composition	Each tablet contains: Nebivolol HCl eq. to Nebivolol…..10mg
	Diary No. Date of R& I & fee	Dy No. 26929: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 10mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 10mg Tablet by Atco Lab Karachi. Reg No. 81562
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved.	
1395.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bystol Tablet 5mg

	Composition	Each tablet contains: Nebivolol HCl eq. to Nebivolol…..5mg
	Diary No. Date of R& I & fee	Dy No. 26928: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 5mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 5mg Tablet by Atco Lab Karachi. Reg No. 81099
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1396.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Bystol Tablet 2.5mg
	Composition	Each tablet contains: Nebivolol HCl eq. to Nebivolol…..2.5mg
	Diary No. Date of R& I & fee	Dy No. 26927: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol 2.5mg) tablets, for oral use by Allergan Sales LLC. **US-FDA** approved
	Me-too status	Bynevol 2.5mg Tablet by Atco Lab Karachi. Reg No. 81561
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1397.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Vidin tablet 50mg+1000mg
	Composition	Each film-coated tablet contains: Vildagliptin…..50mg Metformin hydrochloride BP…..1000mg
	Diary No. Date of R& I & fee	Dy No. 26917: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator'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 by Novartis Pharmaceuticals Australia Pty Ltd. **TGA** approved
	Me-too status	Valiant-M Tablets by Ferozsons Labs., Nowshehra. Reg No. 77485
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with 18 months of shelf life	
1398.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Vidin tablet 50mg+500mg
	Composition	Each film-coated tablet contains: Vildagliptin…..50mg Metformin hydrochloride BP…..500mg
	Diary No. Date of R& I & fee	Dy No. 26917: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Combinations of oral blood glucose lowering drugs

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator'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 by Novartis Pharmaceuticals Australia Pty Ltd. **TGA** approved
	Me-too status	Galmet 50mg/500mg Tablet by Vision Pharma. Reg No. 81905
	GMP status	As recorded for above application
	Remarks of the Evaluator.	The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with 18 months of shelf life	
1399.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Platax tablet 75mg
	Composition	Each film-coated tablet contains: Clopedogrel as bisulphate……..75mg
	Diary No. Date of R& I & fee	Dy No. 26918: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NOUMED CLOPIDOGREL clopidogrel (as hydrogen sulfate) 75 mg film coated tablet blister by Blooming Health Pty Ltd. **TGA** approved
	Me-too status	Disclot Tablets. Reg No. 33906
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1400.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Platax Plus tablet 75mg+81mg
	Composition	Each film-coated bilayer tablet contains: Clopidogrel……..75mg acetylsalicylic acid…….81mg
	Diary No. Date of R& I & fee	Dy No. 26919: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1x14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	DUOPLAVIN 75 mg / 75 mg film-coated tablets. ANSM approved
	Me-too status	Not confirmed
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm revised acetylsalicylic acid …..81mg to acetylsalicylic acid…..75mg. • In Form 5, the firm has claimed Clopedogrel (75mg) and acetylsalicylic acid (81mg) while in Master Formula they have label claim is Clopidogrel as bisulphate (75mg) and acetylsalicylic acid (75mg). • The product in international reference country is film-coated tablet. Justification was asked form the firm for manufacturing of bilayer tablet is required. The firm simply replied that they will manufacture film-coated tablet. They did not revised the composition and manufacturing outlines etc. • The firm did not mention granulation process. However, in 287th meeting similar product was deferred for deliberation with

		remarks of evaluator "Internationally available as film coated tablet prepared by mixing granules of clopidogrel (prepared by wet granulation) and aspirin (prepared by dry granulation)".
	Decision: Deferred for the following: • **Revision of formaulation and all the related documetns in line with the reference product along with submission of applicable fee.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1401.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norbin tablet 5mg
	Composition	Each tablet contains: Amlodipine besilate Ph. Eur. eq. to amlodipine…….5mg
	Diary No. Date of R& I & fee	Dy No. 26912: 29.12.2017 KR 20,000/-: 29.12.2017
	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; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NORVASC amlodipine 5mg (as besilate) tablet by Pfizer Australia Pty Ltd. **TGA** approved
	Me-too status	Sofvasc 5mg Tablets by Wilson's Pharmaceuticals, Islamabad. Reg No. 20182
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1402.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Norbin tablet 10mg
	Composition	Each tablet contains: Amlodipine besilate Ph. Eur. eq. to amlodipine…….10mg
	Diary No. Date of R& I & fee	Dy No. 26913: 29.12.2017 PKR 20,000/-: 29.12.2017
	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; As per SRO
	Approval status of product in Reference Regulatory Authorities.	NORVASC amlodipine 10mg (as besilate) tablet by Pfizer Australia Pty Ltd. **TGA** approved
	Me-too status	Sofvasc 10mg Tablets by Wilson's Pharmaceuticals, Islamabad. Reg No. 20183
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	
1403.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Louric tablet 80mg
	Composition	Each film-coated tablet contains: Febuxostat…….80mg
	Diary No. Date of R& I & fee	Dy No. 26923: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULORIC (febuxostat) 80mg tablet (coated) for oral use by Takeda Pharms USA. **US-FDA** approved
	Me-too status	Adenuric 80mg Tablet by S.J & G Fazul Ellahie (PVt) Ltd, Karachi. Reg No. 67034

	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved with change of brand name	
1404.	Name and address of manufacturer / Applicant	Saibins Pharmaceuticals Plot # 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Louric tablet 40mg
	Composition	Each film-coated tablet contains: Febuxostat…….40mg
	Diary No. Date of R& I & fee	Dy No. 26922: 29.12.2017 PKR 20,000/-: 29.12.2017
	Pharmacological Group	Preparations inhibiting uric acid production
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULORIC (febuxostat) 40mg tablet (coated) for oral use by Takeda Pharms USA. **US-FDA** approved
	Me-too status	Adenuric 40mg Tablet by S.J & G Fazul Ellahie (PVt) Ltd, Karachi. Reg No. 67033
	GMP status	As recorded for above application
	Remarks of the Evaluator.	•
	Decision: Approved	

1405.	Name and address of manufacturer / Applicant	Caraway Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Famcare Tablet 2.5mg
	Composition	Each film-coated tablet contains: Letrozole……..2.5mg
	Diary No. Date of R& I & fee	Dy No. 39445: 30.11.2018 PKR 20,000/-: 30.11.2018
	Pharmacological Group	Aromatase Inhibitors
	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.	Letrozole 2.5 mg, film-coated tablets. **MHRA** approved
	Me-too status	Letzole Tablets 2.5mg. Reg. No. 75805
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• The firm had mentione film-coated tablet and mentioned compositions and step of coating. However, in Form 5, it was "each tablet contain". The firm corrected the label claim to film-coated tablet.
	Decision: Approved	

B. DEFERRED CASES:

1406.	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: Cefoperazone as sodium…1g 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. i) Tablet Section (General/antibiotics) ii) Liquid injectable section (General/antibiotics) iii) Dry injectable section (General/antibiotics) iv) Dry powder injectable (cephalosporins) 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. • The firm has submitted list of eleven (**11**) products applied for contract manufacturing. • 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. • The Board in its 288th meeting deferred the case for revision of Form 5.
	Evaluation by PEC	• The firm submitted revised Form 5.
	Decision: Approved	
1407.	Name and address of manufacturer / Applicant	Tayyab Laboratories Pvt. Ltd. Plot No. 13-A, Street N-5, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Asko Plus Tablet
	Composition	Each film-coated tablet contains: Paracetamol USP…..500mg Hyoscine_N-butyl bromide BP….10mg
	Diary No. Date of R& I & fee	Dy No. 649: 18.11.2016 PKR 20,000/-: 18.11.2016 PKR: 5,000/-; 17.12.2018
	Pharmacological Group	Paracetamol combination with antispasmodic/psycholeptics
	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.	Buscopan Plus film-coated tablet. **DMDI Germany** approved
	Me-too status	Hyo-Plus Tablets. Reg. No. 64452 (film-coated)
	GMP status	The firm was inspected on 22.05.2018 with the following conclusion:

		Keeping in view the above facts, detailed visit of the facility, and supporting documents provided by the company, the firm M/s Tayyab Laboratories (Pvt) Ltd., Plot No, 13, Street No N-5 RCCI, Rawat, Rawalpindi, found complaint as of today and advised to continue with the process of up-gradation with same spirit.
	Remarks of the Evaluator.	• The firm was asked to submit updated Form 5 duly signed by the concerned persons. The firm submitted Form 5. However, undertaking at the end of Form 5 is still missing. • The firm provide new name as "Arreta Pharmaceuticals Pvt. Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Islamabad, Pakistan
	Previous decision	• The registration Board in its 287th meeting deferred the case for submission of undertaking at the end of Form 5.
	Emulation by PEC	• The firm submitted updated duly signed Form 5. • The firm has claimed innovator's specifications. • The firm submitted Rs. 20,000/- dated 19.04.2019. Dy. No. 4039.
	Decision: Approved	
1408.	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: 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
	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.
	Previous decision	The Board in its 288th meeting deferred the case for submission of fee for revision of formulation
		Fee submitted Rs. 5000/-; dated 14.02.2019
	Decision: Approved	
1409.	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: 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.

	Previous decision	The Board in its 288th meeting deferred the case for submission of fee for revision of formulation
		Fee submitted Rs. 5000/-; dated 14.02.2019
	Decision: Approved	

Case No. 02: Registration applications of newly granted DML or New section (Human)

a. New DML

The CLB in its 267th meeting held on 31.12.2018 has been granted DML to the firm. The firm has applied for 07 molecules (14 products) in the dry powder (cephalosporin) section.		
1410.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Rulex Powder for oral suspension 250mg/5ml
	Composition	Each 5ml contain: Cephalexin as monohydrate…… 250mg
	Diary No. Date of R& I & fee	Dy No. 3379: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-generation cephalosporins
	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.	GENRX CEPHALEXIN cefalexin (as monohydrate) 250mg/5mL powder for suspension. **TGA** approved
	Me-too status	Pefalex Suspension 250mg. Reg. No. 80050
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1411.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Rulex Powder for oral suspension 125mg/5ml
	Composition	Each 5ml contain: Cephalexin as monohydrate…… 125mg
	Diary No. Date of R& I & fee	Dy No. 3378: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-generation cephalosporins
	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.	GENRX CEPHALEXIN cefalexin (as monohydrate) 125mg/5mL powder for suspension. **TGA** approved
	Me-too status	Pefalex Suspension 125mg. Reg. No. 80049
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1412.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Rulex Powder for oral drops 100mg/ml
	Composition	Each ml contains: Cephalexin as monohydrate…… 100mg
	Diary No. Date of R& I & fee	Dy No. 3411: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-generation cephalosporins
	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.	Kefex 100 mg / ml granules for oral suspension. Approved in **Finland** KEFLEX EQ 100mg base/ml discontinued in USFDA but not for safety or efficacy reasons.
	Me-too status	KEFLEX PAED, 100MG DRP. Reg. No. 1071

	GMP status	New DML
	Remarks of the Evaluator.	• Kefexin in Finland has Pharmaceutical form as "Granules for oral suspension: orange-yellow powder" and the salt from does not depict hydrate from of API. Moreover, there is no description for drops or dropper. The nature and content of container are 30 and 50 ml: glass bottle (type III glass) and polyethylene / polypropylene closure. It is pertinent to mention that Cefaclor "for suspension" and oral drop have been mentioned separate in the same strength in AIFA, wherein the latter is supplied with dropper. Only the following statement is present: With the syringe for dispensing, an adapter from a separate Orion Pharma can be attached to the bottle mouth adapter / syringe package • The Board in tis 271th meeting has approved Nufex Pediatric drop 100mg/ml on the basis of KEFLEX EQ 100mg base/ml discontinued in USFDA but not for safety or efficacy reasons, The SmPC is not available to get the requisite information.
	Decision: Approved	
1413.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Micef Powder for oral suspension 200mg/5ml
	Composition	Each 5ml contain: Cefixime as trihydrate…… 200mg
	Diary No. Date of R& I & fee	Dy No. 3381: 24.01.2019 PKR 20,000/-: 24.01.2019
	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.	SUPRAX® (cefixime) for oral suspension. **USFDA** approved
	Me-too status	Elixime Dry Suspension 200mg. Reg. No. 53730
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1414.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Micef Powder for oral suspension 100mg/5ml
	Composition	Each 5ml contain: Cefixime as trihydrate…… 100mg
	Diary No. Date of R& I & fee	Dy No. 3380: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	Third-generation cephalosporins
	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.	Cefixime 100 mg/5 ml Powder for Oral Suspension. MHRA approved
	Me-too status	Elixime Dry Suspension 100mg. Reg. No. 53729
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1415.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Cefrid Powder for oral suspension 250mg/5ml
	Composition	Each 5ml contain:

		Cephradine as monhydrate…… 250mg
	Diary No. Date of R& I & fee	Dy No. 3371: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30 ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Hidin Oral Suspension 250mg. Reg. No. 80036
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Deferred for Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.	
1416.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Cefrid Powder for oral suspension 125mg/5ml
	Composition	Each 5ml contain: Cephradine as monhydrate…… 125mg
	Diary No. Date of R& I & fee	Dy No. 3370: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-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.	Could not be confirmed
	Me-too status	Hidin Oral Suspension 125mg. Reg. No. 80037
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Decision: Deferred for Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.	
1417.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Furox Powder for oral suspension 125mg/5ml
	Composition	Each 5ml contain: Cefuroxime as axetil…… 125mg
	Diary No. Date of R& I & fee	Dy No. 3372: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-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.	Zinnat granules for Suspension 125mg/5ml. **MHRA** approved
	Me-too status	Kefzy Suspension 125mg/5ml. Reg. No. 82756
	GMP status	New DML
	Remarks of the Evaluator.	• The reference product contains granules for oral suspension. However, the provided master formula and manufacturing outlines does not depict granule formation. The firm was asked for justification/ clarification. The firm provided another reference product, which could be verified.
	Decision: Deferred for confirmation of approval status in reference regulatory authoritis.	
1418.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Furox Powder for oral suspension 250mg/5ml
	Composition	Each 5ml contain: Cefuroxime as axetil…… 250mg
	Diary No. Date of R& I & fee	Dy No. 3373: 24.01.2019 PKR 20,000/-: 24.01.2019

	Pharmacological Group	First-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.	Could not be confirmed
	Me-too status	Kefzy Suspension 250mg/5ml. Reg. No. 82757
	GMP status	New DML
	Remarks of the Evaluator.	The reference product contains granules for oral suspension. However, the provided master formula and manufacturing outlines does not depict granule formation. The firm was asked for justification/ clarification. The firm provided another reference product, which could not be verified.
	Decision: Deferred for Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.	
1419.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Cecil Powder for oral suspension 125mg/5ml
	Composition	Each 5ml contain: Cefadroxil as monohydrate…… 125mg
	Diary No. Date of R& I & fee	Dy No. 3376: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-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.	Biodroxil 125 mg /5 ml - Pulver zur Herstellung einer Suspension zum Einnehmen (Biodroxil 125 mg / 5 ml - Powder for oral suspension). **AGES** approved
	Me-too status	Evacef Suspension 125mg. Reg. No. 11213
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1420.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Cecil Powder for oral suspension 250mg/5ml
	Composition	Each 5ml contain: Cefadroxil as monohydrate…… 250mg
	Diary No. Date of R& I & fee	Dy No. 3377: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-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.	Cefadroxil 250 mg/5 ml **powder** for oral suspension. USFDA approved
	Me-too status	Evacef Suspension 250mg. Reg. No. 11214
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1421.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Ceficlor Powder for oral suspension 250mg/5ml
	Composition	Each 5ml contain: Cefaclor as monohydrate…… 250mg
	Diary No. Date of R& I & fee	Dy No. 3375: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	Second-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.	Cefaclor 250mg/5ml powder for Suspension. **MHRA** approved
	Me-too status	Eclor Oral Suspension 250mg/5ml Dry Suspension. Reg. No. 83945
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved.	
1422.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Ceficlor Powder for oral suspension 125mg/5ml
	Composition	Each 5ml contain: Cefaclor as monohydrate…… 125mg
	Diary No. Date of R& I & fee	Dy No. 3374: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	Second-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.	Cefaclor 125mg/5ml powder for Suspension. **MHRA** approved
	Me-too status	Eclor Oral Suspension 125mg/5ml Dry Suspension. Reg. No. 83946
	GMP status	New DML
	Remarks of the Evaluator.	•
	Decision: Approved	
1423.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Ceficlor Powder for oral drops 50mg/ml
	Composition	Each ml contains: Cefaclor as monohydrate…… 50mg
	Diary No. Date of R& I & fee	Dy No. 3410: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	Second-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.	PANACEF 50 mg/ml gocce orali, sospensione. AIFA approved
	Me-too status	Cefalor Drops 50mg/ml. Reg. No. 34368
	GMP status	New DML
	Remarks of the Evaluator.	• The reference product is oral drops, suspension with direction for reconstitution.
	Decision: Approved	
The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. The firm has applied for 10 molecules (21 products) in the capsule section.		
1424.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Tecso Capsule 20mg
	Composition	Each capsule contains: Esomeprazole magnesium trihydrate (enteric coated pellets) eq. to esomeprazole…… 20mg
	Diary No. Date of R& I & fee	Dy No. 1726: 14.01.2019 PKR 20,000/-: 14.01.2019
	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.	NEXIUM® (esomeprazole magnesium) 20mg delayed-release capsules (in the form of enteric-coated granules). USFDA approved
	Me-too status	Obpra Capsule 20mg by Obson Pharma. Reg. No. 54165
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion. • The pellets have been assayed on the basis of esopemrazole Mg (%) as trihydrate.
	Decision: Deferred for further delibration regarding assay on the basis of esopemrazole Mg (%) as trihydrate	
1425.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Tecso Capsule 40mg
	Composition	Each capsule contains: Esomeprazole magnesium trihydrate (enteric coated pellets) eq. to esomeprazole…… 40mg
	Diary No. Date of R& I & fee	Dy No. 1727: 14.01.2019 PKR 20,000/-: 14.01.2019
	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.	NEXIUM® (esomeprazole magnesium) 40mg delayed-release capsules (in the form of enteric-coated granules). USFDA approved
	Me-too status	Obpra Capsule 40mg by Obson Pharma. Reg. No. 54166
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion. • The pellets have been assayed on the basis of esopemrazole Mg (%) as trihydrate.
	Decision: Deferred for further delibration regarding assay on the basis of esopemrazole Mg (%) as trihydrate	
1426.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Ovic Capsule 20mg
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets)…… 20mg
	Diary No. Date of R& I & fee	Dy No. 1713: 14.01.2019 PKR 20,000/-: 14.01.2019
	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.	Losec 20 mg hard gastro-resistant capsules by AstraZeneca UK Ltd., Approved by **MHRA**
	Me-too status	Omecap Capsule by Next Pharmaceutical Products (Pvt) Ltd, Lahore. Reg. No. 84493
	GMP status	The firm has been granted DML on the basis of inspection

		13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved	
1427.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Ovic Capsule 40mg
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets)…… 40mg
	Diary No. Date of R& I & fee	Dy No. 1706: 14.01.2019 PKR 20,000/-: 14.01.2019
	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.	Losec 40 mg hard gastro-resistant capsules by AstraZeneca UK Ltd., Approved by **MHRA**
	Me-too status	Omecap Capsule by Next Pharmaceutical Products (Pvt) Ltd, Lahore. Reg. No. 84494
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved	
1428.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Syolex Capsule 20mg
	Composition	Each capsule contains: Duloxetine HCl (enteric coated pellets) eq. to duloxetine...20mg
	Diary No. Date of R& I & fee	Dy No. 1705: 14.01.2019 PKR 20,000/-: 14.01.2019 PKR 5,000/-: 04.03.2019
	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.	Dutor 20 mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too status	Oxcym DR 20 mg Capsule. Reg. No. 76164
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The reference product contains doluxetine HCl (enteric coated pellets) eq. to Doluxetine…20mg. The firm revised the salt form in label claim in Form 5 along with submission of Rs. 5000/- fee.
	Decision: Approved.	
1429.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Syolex Capsule 30mg
	Composition	Each capsule contains: Duloxetine HCl (enteric coated pellets) eq. to duloxetine..30mg
	Diary No. Date of R& I & fee	Dy No. 1716: 14.01.2019 PKR 20,000/-: 14.01.2019

		PKR 5,000/-: 04.03.2019
	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.	Dutor 30 mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too status	Oxcym DR 30 mg Capsule. Reg. No. 53101
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The reference product contains doluxetine HCl (enteric coated pellets) eq. to Doluxetine…20mg. The firm revised the salt form in label claim in Form 5 along with submission of Rs. 5000/- fee.
	Decision: Approved	
1430.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Syolex Capsule 40mg
	Composition	Each capsule contains: Duloxetine HCl(enteric coated pellets) eq. to duloxetine..40mg
	Diary No. Date of R& I & fee	Dy No. 1704: 14.01.2019 PKR 20,000/-: 14.01.2019 PKR 5,000/-: 04.03.2019
	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.	Dutor 40 mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too status	Worth capsule 40mg. Reg. No. 68816
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The reference product contains doluxetine HCl (enteric coated pellets) eq. to Doluxetine…20mg. The firm revised the salt form in label claim in Form 5 along with submission of Rs. 5000/- fee.
	Decision: Approved	
1431.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Ezocin Capsule 250mg
	Composition	Each capsule contains: Azithromycin as dihydrate…… 250mg
	Diary No. Date of R& I & fee	Dy No. 1734: 14.01.2019 PKR 20,000/-: 14.01.2019
	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 250 mg Capsules. **MHRA** approved
	Me-too status	Azofas 250mg Capsules. Reg. No. 60291
	GMP status	The firm has been granted DML on the basis of inspection

		13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis. The firm submitted that they will purchase the same.
	Decision: Deferred for amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis.	
1432.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Thiovin Capsule 4mg
	Composition	Each capsule contains: Thiocolchicoside…….4mg
	Diary No. Date of R& I & fee	Dy No. 1728: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacture's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MIOREL 4 mg capsule. **ANSM** approved
	Me-too status	Muscucoside capsule 4mg. Reg. No. 81656
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision: Approved with innovator's specfications.	
1433.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Iborine Capsule 200mg
	Composition	Each capsule contains: Mebeverine HCl…….200mg
	Diary No. Date of R& I & fee	Dy No. 1735: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacture's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	COLOFAC® MR 200mg Capsules. **MHRA** approved
	Me-too status	Mebrest-200 Capsule. Reg. No. 80547
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision: Deferred for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)	
1434.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Velcox Capsule 100mg

	Composition	Each capsule contains: Celecoxib…….100mg
	Diary No. Date of R& I & fee	Dy No. 1732: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacture's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Celebrex 100 mg capsules, hard by Pfizer Limited. **MHRA** approved
	Me-too status	Bexicox 100 Capsule by Medipak Ltd, Lahore. R.No. 23946
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same. • Celecoxib also lies in L01 class with ATC code L01XX33, for which a dedicated or self-contained facility is required as per decision of 282nd meeting of Registration Board.
	Decision: Apporved with Innovator's Specification.	
1435.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Velcox Capsule 200mg
	Composition	Each capsule contains: Celecoxib…….200mg
	Diary No. Date of R& I & fee	Dy No. 1733: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacture's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Celebrex 200 mg capsules, hard by Pfizer Limited. **MHRA** approved
	Me-too status	Bexicox 200 Capsule by Medipak Ltd, Lahore. R. No. 23947
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same. • Celecoxib also lies in L01 class with ATC code L01XX33, for which a dedicated or self-contained facility is required as per decision of 282nd meeting of Registration Board.
	Decision: Apporved with Innovator's Specification.	
1436.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Enxic-F Capsule 3/25mg
	Composition	Each capsule contains: Olanzapine…….3mg Fluoxetine as HCl…..25mg
	Diary No. Date of R& I & fee	Dy No. 1714: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Antipsychotics and 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.	SYMBYAX (olanzapine and fluoxetine) 3/25mg capsules. **US-FDA** approved

	Me-too status	Co-Depricap 3/25 Capsule by NabiQasim Karachi.R.#076136
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	•
	Decision: Approved	
1437.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Enxic-F Capsule 6/25mg
	Composition	Each capsule contains: Olanzapine…….6mg Fluoxetine as HCl…..25mg
	Diary No. Date of R& I & fee	Dy No. 1715: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Antipsychotics and 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.	SYMBYAX (olanzapine and fluoxetine) 6/25mg capsules. **US-FDA** approved
	Me-too status	Co-Depricap 6/25 Capsule by NabiQasim Karachi. R.#076135
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	•
	Decision: Approved	
1438.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Enxic-F Capsule 12/25mg
	Composition	Each capsule contains: Olanzapine…….12mg Fluoxetine as HCl…..25mg
	Diary No. Date of R& I & fee	Dy No. 1729: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Antipsychotics and 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.	SYMBYAX (olanzapine and fluoxetine) 12/25mg capsules. **US-FDA** approved
	Me-too status	Amprexa-F 12/25mg Capsule. Reg. No. 76751
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	•
	Decision: Approved	
1439.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 150mg
	Composition	Each capsule contains: Pregabalin…….150mg
	Diary No. Date of R& I & fee	Dy No. 1724: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 150 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 150mg Capsule. Reg. No. 82184
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.

	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision: Deferred for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)	
1440.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 100mg
	Composition	Each capsule contains: Pregabalin…….100mg
	Diary No. Date of R& I & fee	Dy No. 1723: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 100 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 100mg Capsule. Reg. No. 82185
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision: Deferred for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)	
1441.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 75mg
	Composition	Each capsule contains: Pregabalin…….75mg
	Diary No. Date of R& I & fee	Dy No. 1722: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 75mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision: Deferred for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)	
1442.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 50mg
	Composition	Each capsule contains: Pregabalin…….50mg
	Diary No. Date of R& I & fee	Dy No. 1721: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5

	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 50mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Decision: Deferred for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)	
1443.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Vensor Capsule 75mg
	Composition	Each capsule contains: Venlafexine HCl (extended release pellets) eq. to Venlafexine…….75mg
	Diary No. Date of R& I & fee	Dy No. 1731: 14.01.2019 PKR 20,000/-: 14.01.2019
	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.	EFFEXOR XR® (venlafaxine Extended-Release) 75mg Capsules. **USFDA** approved
	Me-too status	Vfx Capsule 75mg. Reg. No. 82659
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved	
1444.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Vensor Capsule 37.5mg
	Composition	Each capsule contains: Venlafexine HCl (extended release pellets) eq. to Venlafexine…….37.5mg
	Diary No. Date of R& I & fee	Dy No. 1730: 14.01.2019 PKR 20,000/-: 14.01.2019
	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.	EFFEXOR XR® (venlafaxine Extended-Release) 37.5mg Capsules. **USFDA** approved
	Me-too status	Venomap-SR 37.5mg Capsule. Reg. No. 61332
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	
	Decision:Approved	

M/s. IQRA Pharmaceuticals, Islamabad (New License)

Following registration dossiers have been received dated 07/03/ 2019 stating that the firm has been granted approval of new DML by way of formulation by Central Licensing Board in its 269th meeting for following thirteen (13)sections

1. Tablet section (General)
2. Capsule section (General)
3. Cream/Ointment/Gel section
4. Oral liquid syrup section (General)
5. Dry powder oral suspension section (General)
6. Liquid Sterile Ampoule section (General)
7. Liquid Sterile Ampoule section (psychotropic)
8. Tablet section (psychotropic)
9. Sterile Ampoule section (steroid)
10. Sterile infusion/small volume vial section (General)
11. *Dry Powder for Injection (*Cephalosporin*)*
12. Capsule section (Cephalosporin)
13. Dry powder oral suspension section (Cephalosporin)

The following applications have been evaluated and presented before the Board

Sr.#	Section	No. of products	No. of molecules
1.	Tablet section (General)	14	10
2.	Capsule section (General)	15	8
3.	Cream /Ointment/Gel Section	05	05
4.	Liquid Sterile Ampoule section (psychotropic)	08	07
5.	Tablet section (psychotropic)	17	08
6.	Sterile Ampoule section (steroid)	04	03

Tablet (General) Section (Human): 10 Molecules/14 Products

1452.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Qix 10mg Tablet
	Composition	Each film coated tablet contains: Escitalopram as Oxalate…10mg
	Diary No. Date of R & I & Fee	Dy No. 15569: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x14's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Lexapro® (escitalopram) 10mg film-coated Tablets, for oral use. **USFDA** approved
	Me-too Status	Dipgo Tablet 10mg, film-coated. Reg. No. 85715
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1453.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Losu 25mg Tablets
	Composition	Each tablet contains: Levosulpiride…25mg
	Diary No. Date of R & I & Fee	Dy No. 15576: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack Size & Demanded Price	10's, 20's; As per SRO

	Approval Status of product in Reference Regulatory Authorities	LEVOPRAID® 25 mg Tablets by TEOFARMA Srl. Approved by AIFA
	Me-too Status	Sulvo Tablets 25mg. Reg. No. 31747
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1454.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Losu 50mg Tablets
	Composition	Each tablet contains: Levosulpiride…50mg
	Diary No. Date of R & I & Fee	Dy No. 15577: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack Size & Demanded Price	10's, 20's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	LEVOPRAID® 50 mg Tablets by TEOFARMA Srl. Approved by AIFA
	Me-too Status	Sulvo Tablets 50mg. Reg. No. 31748
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1455.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	SETRIZ 10mg Tablets
	Composition	Each film coated tablet contain: Cetirizine dihydrochloride…….10mg
	Diary No. Date of R & I & Fee	Dy No. 15516: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's,20's ,100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cetec 10 mg film-coated tablets (Cetirizine hydrochloride). MHRA Approved
	Me-too status	Farozen Tablet. Reg. No. 67914 (does not depict film-coating)
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1456.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Furbi 100mg Tablets
	Composition	Each sugar-coated tablet contain: Flurbiprofen…100mg
	Diary No. Date of R & I & Fee	Dy No. 15537: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's,2x10's, 6x5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Flurbiprofen 100 mg sugar-coated tablets by Mylan Products Ltd. **MHRA** approved
	Me-too status	Flunifen Tablet by Unipharma (Pvt) Ltd. Reg. No. 81350
	GMP Status	New License
	Remarks of the Evaluator	The firm revised of formulation (label claim, master formula, and manufacturing outlines) to sugar-coated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved	

1457.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Moxo 400mg Tablets
	Composition	Each film coated tablet contain: Moxifloxacin as HCl…400mg
	Diary No. Date of R & I & Fee	Dy No. 15538: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Floroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Avelox® 400mg film-coated tablets. **MHRA** approved
	Me-too status	Navilox 400mg Tablet. Reg. No. 85166
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1458.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	I-Quin 250mg Tablets
	Composition	Each film coated tablet contain: Levofloxacin as hemihydrate……250mg
	Diary No. Date of R & I & Fee	Dy No. 15574: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Floroquinolones
	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.	Evoxil 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Levolis 250mg Tablets. Reg. No. 85178
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1459.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	I-Quin 500mg Tablets
	Composition	Each film coated tablet contain: Levofloxacin as hemihydrate……500mg
	Diary No. Date of R & I & Fee	Dy No. 15575: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Floroquinolones
	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.	Evoxil 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Levoquin 500mg Tablet. Reg. No. 85206
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1460.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Piro-Bd 20mg Tablet
	Composition	Each film coated tablet contain: Piroxicam as betacyclodextrin …20mg
	Diary No. Date of R & I & Fee	Dy No. 15575: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (oxicams)

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specification.
	Pack size & Demanded Price	1x10's; 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	Piram-BX Tablets 20mg. Reg. No. 80594
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications	
1461.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	D-Fo SR 100mg Tablet
	Composition	Each prolonged release tablet contains: Diclofenac Sodium…100mg
	Diary No. Date of R & I & Fee	Dy No. 15513: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x10's, 3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Dicloflex Retard 100 mg prolonged release tablet. **MHRA** approved
	Me-too status	Diclorax 100mg Tablet. Reg. # 85498
	GMP Status	New License
	Remarks of the Evaluator	• The firm revised the formulation to prolonged release tablet along with submission of applicable fee Rs. 5000/-. • Revision of all compostion, manufacturing outlines required. • The reference product contains sub-coat of Copovidone and Sucrose, and Pigmented film coat of Opadry 02B24025. The dossier does not depict the same.
	Decision: Deferred for revision of compostion and manufacturing outlines.	
1462.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Tam-P 37.5/325 mg Tablets
	Composition	Each film-coated tablet contains: Tramadol Hcl…37.5mg Paracetamol…325mg
	Diary No. Date of R & I & Fee	Dy No. 15620: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) coated tablets, for oral use. **USFDA** approved
	Me-too status	Tril-P Tablet. Reg. No. 78181
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1463.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Roxil 250mg Tablets
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl…250mg
	Diary No. Date of R & I & Fee	Dy No. 15535: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Floroquinolones
	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.	Ciprofloxacin 250 mg film coated tablets. **MHRA** approved
	Me-too status	C-Flox 250mg Tablet. Reg. No. 83720
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1464.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Roxil 500mg Tablets
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl…500mg
	Diary No. Date of R & I & Fee	Dy No. 15536: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Floroquinolones
	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.	Ciprofloxacin 500 mg film coated tablets. **MHRA** approved
	Me-too status	C-Flox 500mg Tablet. Reg. No. 83719
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1465.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Roxil 750mg Tablets
	Composition	Each film coated tablet contains: Ciprofloxacin as HCl…750mg
	Diary No. Date of R & I & Fee	Dy No. 15537: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Floroquinolones
	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.	Ciprofloxacin 750 mg film coated tablets. **MHRA** approved
	Me-too status	CIP Tablets 750 mg. Reg. No. 79347
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
Capsule (General) Section (Human): 08 Molecules/15 Products		
1466.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Zito 250mg Capsule
	Composition	Each hard gelatin capsule contains: Azithromycin as Dihydrate……250mg
	Diary No. Date of R & I & Fee	Dy No. 15550: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x6's, 10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Azithromycin 250 mg Capsules. **MHRA** approved
	Me-too Status	Azofas 250mg Capsules. Reg. No. 60291
	GMP Status	New License

	Remarks of the Evaluator	• The USP has mentioned amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis. The firm submitted that they will purchase the said electrode.
	Decision: Deferred for provision of amperometric electrochemical detector with dual glassy carbon electrodes for assay/analysis.	
1467.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Nero-P 25mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…25mg
	Diary No. Date of R & I & Fee	Dy No. 15520: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	2x7's, 2x14's, 30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Alzain 25 mg Capsules, Hard. **MHRA** approved
	Me-too Status	Zeegap 25 mg Capsules. Reg. No. 47357
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
1468.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Nero-P 50mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…50mg
	Diary No. Date of R & I & Fee	Dy No. 15540: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	2x7's, 2x14's, 30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Alzain 50 mg Capsules, Hard. **MHRA** approved
	Me-too Status	Scirica 50mg Capsule. Reg. No. 82187
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
1469.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Nero-P 75mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…75mg
	Diary No. Date of R & I & Fee	Dy No. 15545: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	2x7's, 2x14's, 30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Alzain 75 mg Capsules, Hard. **MHRA** approved
	Me-too Status	Scirica 75mg Capsule. Reg. No. 82186
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	

1470.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Nero-P 100mg Capsule
	Composition	Each hard gelatin capsule contains: Pregabalin…100mg
	Diary No. Date of R & I & Fee	Dy No. 15542: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack Size & Demanded Price	2x7's, 2x14's, 30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Alzain 100 mg Capsules, Hard. **MHRA** approved
	Me-too Status	Scirica 100mg Capsule. Reg. No. 82185
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved with innovator's specifications.	
1471.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Piriq 20mg Capsule
	Composition	Each hard gelatin capsule contains: Piroxicam…20mg
	Diary No. Date of R & I & Fee	Dy No. 15578: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Antiinflammatory and antirheumatic products, non-steroids (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	FELDENE 20mg capsules. **MHRA** approved
	Me-too Status	FELDENE 20mg capsules. Reg. No. 6349
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1472.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Fentiq 150mg Capsule
	Composition	Each hard gelatin capsule contains: Fluconazole…150mg
	Diary No. Date of R & I & Fee	Dy No. 15551: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Antimycotics for systemic use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	1x10's, 20's, 100's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Fluconazole 150mg capsule. **MHRA** approved
	Me-too Status	Fungon Capsules 150mg. Reg. No. 55353
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1473.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Reso 40mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Esomeprazole magnesium trihydrate Eq. to Esomeprazole…40mg
	Diary No. Date of R & I & Fee	Dy No. 15549: 07.03.2019 Rs. 20,000/-: 06.03.2019

	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x7, 20's, 100's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	NEXIUM® (esomeprazole magnesium) 40mg delayed-release capsules (in the form of enteric-coated granules). USFDA approved
	Me-too Status	Obpra Capsule 20mg by Obson Pharma. Reg. No. 54166
	GMP Status	New License Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator	• The pellets have been assayed on the basis of esopemrazole Mg (%) as trihydrate.
	Decision: Approved	
1474.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Reso 20mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Esomeprazole magnesium trihydrate Eq. to Esomeprazole…20mg
	Diary No. Date of R & I & Fee	Dy No. 15548: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	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	NEXIUM® (esomeprazole magnesium) 40mg delayed-release capsules (in the form of enteric-coated granules). USFDA approved
	Me-too Status	Obpra Capsule 20mg by Obson Pharma. Reg. No. 54165
	GMP Status	New License Source of pellets: The firm M/s Surge Pharma was inspected on 22.02.2018 and 04.05.2018, wherein it was concluded that the firm has maintained fair level of GMP compliance.
	Remarks of the Evaluator	• The pellets have been assyed on the basis of esopemrazole Mg (%) as trihydrate. • The pellets of Sruge of Pharma have been assayed and tested for stability with in-house specifications.
	Decision: Approved	
1475.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	G-OM 20mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Omeprazole Eq. to Omeprazole….20mg
	Diary No. Date of R & I & Fee	Dy No. 15546: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	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	Losec 20 mg hard gastro-resistant capsules by AstraZeneca UK Ltd., Approved by **MHRA**
	Me-too Status	Omecap Capsule by Next Pharmaceutical Products (Pvt) Ltd, Lahore. Reg. No. 84493
	GMP Status	New License Sourcce of pellets: The firm M/s Vision Pharmaceuticals was

		inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator	•
	Decision: Approved	
1476.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	G-OM 40mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Omeprazole Eq. to Omeprazole….40mg
	Diary No. Date of R & I & Fee	Dy No. 15547: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	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	Losec 40 mg hard gastro-resistant capsules by AstraZeneca UK Ltd., Approved by **MHRA**
	Me-too Status	Omecap Capsule by Next Pharmaceutical Products (Pvt) Ltd, Lahore. Reg. No. 84494
	GMP Status	New License Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator	•
	Decision: Approved	
1477.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Sero-T 20mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Duloxetine HCl Eq. to Duloxetine…20mg
	Diary No. Date of R & I & Fee	Dy No. 15543: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x7's, 4x7's, 1x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Depalta 20mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too Status	Oxcym DR 20 mg Capsule. Reg. No. 76164
	GMP Status	New License Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator	•
	Decision: Approved	
1478.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Sero-T 30mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Duloxetine HCl Eq. to Duloxetine…30mg
	Diary No. Date of R & I & Fee	Dy No. 15544: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x7's, 4x7's, 1x10's; as per SRO

	Approval Status of product in Reference Regulatory Authorities	Depalta 30mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too Status	Oxcym DR 30 mg Capsule. Reg. No. 53101
	GMP Status	New License Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator	•
	Decision: Approved	
1479.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Sero-T 60mg Capsule
	Composition	Each hard gelatin capsule contains: Enteric coated pellets of Duloxetine HCl Eq. to Duloxetine…60mg
	Diary No. Date of R & I & Fee	Dy No. 15545: 07.03.2019 Rs. 20,000/-: 06.03.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x7's, 4x7's, 1x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Depalta 60mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too Status	Oxcym DR 60 mg Capsule. Reg. No. 53102
	GMP Status	New License Sourcce of pellets: The firm M/s Surge Pharma was inspected on 22.02.2018 and 04.05.2018, wherein it was concluded that the firm has maintained fair level of GMP compliance.
	Remarks of the Evaluator	•
	Decision: Approved	
1480.	**Name and address of manufacturer / Applicant**	**M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Brand Name + Dosage Form + Strength	Doxy-Liq 100mg Capsule
	Composition	Each hard gelatin capsule contains: Doxycycline as Hyclate…100mg
	Diary No. Date of R & I & Fee	Dy No. 15565: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Tetracyclines
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 20's, 30's, 100's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Doxycycline 100mg Capsules. **MHRA** approved
	Me-too Status	Sodox Capsule 100mg. Reg. No. 84061
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
Tablet (Psychotropic) Section (Human): 08 Molecules/17 Products		
1481.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Al-Proz 0.25mg Tablet
	Composition	Each tablet contains: Alprazolam…0.25mg
	Diary No. Date of R & I & Fee	Dy No. 15604: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Xanax 250 microgram Tablets. MHRA approved
	Me-too Status	Lamzo 0.25mg Tablet. Reg. No. 57867
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1482.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Al-Proz 0.5mg Tablet
	Composition	Each tablet contains: Alprazolam…0.5mg
	Diary No. Date of R & I & Fee	Dy No. 15605: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Xanax 500 microgram Tablets. MHRA approved
	Me-too Status	Lamzo 0.5mg Tablet. Reg. No. 57868
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1483.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Al-Proz 1mg Tablet
	Composition	Each tablet contains: Alprazolam…01mg
	Diary No. Date of R & I & Fee	Dy No. 15606: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	ALPRAZOLAM-GA alprazolam 1mg tablet. TGA approved
	Me-too Status	Lamzo 1mg Tablet. Reg. No. 57869
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1484.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Al-Proz 2mg Tablet
	Composition	Each tablet contains: Alprazolam…2mg
	Diary No. Date of R & I & Fee	Dy No. 15607: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	ALPRAZOLAM-GA alprazolam 2mg tablet. TGA approved
	Me-too Status	M-Zolam 2mg Tablet. Reg. No. 58406
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	

1485.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Lorvan 1mg Tablet
	Composition	Each tablet contains: Lorazepam…1mg
	Diary No. Date of R & I & Fee	Dy No. 15601: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Ativan® (lorazepam) 1 mg Tablets. USFDA approved
	Me-too Status	Lorze 1mg Tablet. Reg. No. 61233
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1486.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Lorvan 2mg Tablet
	Composition	Each tablet contains: Lorazepam…1mg
	Diary No. Date of R & I & Fee	Dy No. 15600: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Ativan® (lorazepam) 2 mg Tablets. USFDA approved
	Me-too Status	Lorze 2mg Tablet. Reg. No. 61234
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1487.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Dezopam 5mg Tablet
	Composition	Each tablet contains: Diazepam…5mg
	Diary No. Date of R & I & Fee	Dy No. 15612: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100's, 3x10's, 1000's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Diazepam 5 mg Tablets. MHRA approved
	Me-too Status	Dalium 5mg Tablet. Reg. No. 61854
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1488.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Dezopam 10mg Tablet
	Composition	Each tablet contains: Diazepam…10mg
	Diary No. Date of R & I & Fee	Dy No. 15608: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	100's, 3x10's, 1000's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Diazepam 10 mg Tablets. MHRA approved
	Me-too Status	Dalium 10mg Tablet. Reg. No. 61855
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1489.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Epitop 25mg Tablets
	Composition	Each film-coated tablet contains: Topiramate…25mg
	Diary No. Date of R & I & Fee	Dy No. 15505: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other antiepileptics
	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	Topamax® 25 mg film-coated tablets. **MHRA** approved
	Me-too Status	Erbro 25mg Tablet Tablet. Reg. No. 80384
	GMP Status	New License
	Remarks of the Evaluator	• Topiramate does not look to be psychotropic drug.
	Decision: Deferred for consideration on its turn.	
1490.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Epitop 50mg Tablets
	Composition	Each film-coated tablet contains: Topiramate…50mg
	Diary No. Date of R & I & Fee	Dy No. 15506: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other antiepileptics
	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	Topamax® 50 mg film-coated tablets. **MHRA** approved
	Me-too Status	Topister Tablet 50mg. Reg. No. 82548
	GMP Status	New License
	Remarks of the Evaluator	• Topiramate does not look to be psychotropic drug.
	Decision: Deferred for consideration on its turn	
1491.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Co-Pam 1mg Tablet
	Composition	Each tablet contains: Clonazepam…1mg
	Diary No. Date of R & I & Fee	Dy No. 15582: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	KLONOPIN TABLETS 1mg. **USFDA** approved
	Me-too Status	Curo 1mg Tablets. Reg. No. 65700
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	

1492.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Co-Pam 0.5mg Tablet
	Composition	Each tablet contains: Clonazepam…0.5mg
	Diary No. Date of R & I & Fee	Dy No. 15582: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	KLONOPIN TABLETS 0.5mg. **USFDA** approved
	Me-too Status	Cozepam 0.5mg Tablet. Reg. No. 64716
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1493.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Co-Pam 2mg Tablet
	Composition	Each tablet contains: Clonazepam…2mg
	Diary No. Date of R & I & Fee	Dy No. 15599: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	KLONOPIN TABLETS 2mg. **USFDA** approved
	Me-too Status	Cozepam 2mg Tablet. Reg. No. 64715
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1494.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Zol-P 10mg Tablet
	Composition	Each film-coated tablet contains: Zolpidem tartrate…10mg
	Diary No. Date of R & I & Fee	Dy No. 15596: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine related drugs
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Stilnoct 10mg film-coated tablets. **MHRA** approved
	Me-too Status	Ensomie Tablet 10mg. Reg. No. 85026
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1495.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Brozil 1.5mg Tablets
	Composition	Each tablet contains: Bromazepam…1.5mg
	Diary No. Date of R & I & Fee	Dy No. 15602: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	BROMAZEPAM ARROW 1.5 mg tablets. **ANSM** approved
	Me-too Status	Yazd 1.5mg Tablet. Reg. No. 71219
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1496.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Brozil 3mg Tablets
	Composition	Each tablet contains: Bromazepam…3mg
	Diary No. Date of R & I & Fee	Dy No. 15603: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 3x10's, 5x10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	LEXOTAN bromazepam 3mg tablet. **TGA** approved
	Me-too Status	Arbro Tablet 3mg. Reg. No. 78887
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1497.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Bital 30mg Tablet
	Composition	Each tablet contains: Phenobarbital……..……. 30 mg
	Diary No. Date of R & I & Fee	Dy No. 15597: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Barbiturates and derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100's, 60's, 1000's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Phenobarbital 30mg Tablets. **MHRA** approved
	Me-too Status	Fenotal 30 mg Tablets. Reg. No. 79323
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
Liquid Injectable (Steroidal hormones) Section (Human): 03 Molecules/04 Products		
1498.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Tipomed 80mg/ml Injection
	Composition	Each 1ml ampoule contains: Methylprednisolone Acetate…80mg
	Diary No. Date of R & I & Fee	Dy No. 15526: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x1ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	DEPO-MEDROL® (methylprednisolone acetate injectable suspension, USP) single dose vial (1ml). USFDA approved
	Me-too Status	Radilem Suspension 80mg (each vial contains; Sterile, micronized methylprednisolone acetate.80.0mg). R.#033424

	GMP Status	New License
	Remarks of the Evaluator	• The firm has mentioned injection dosage form. The composition dosage from is injectable suspension.
	Decision: Approved	
1499.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Tipomed 40mg/ml Injection
	Composition	Each 1ml ampoule contains: Methylprednisolone Acetate…40mg
	Diary No. Date of R & I & Fee	Dy No. 15529: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x1ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	DEPO-MEDROL® (methylprednisolone acetate injectable suspension, USP) single dose vial (1ml). USFDA approved
	Me-too Status	Co-Sterol Injection (1 ml suspension in vial). Reg. No. 63094
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1500.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Trimacort 40mg Injection
	Composition	Each 1ml ampoule contains: Triamcinolone Acetonide…40mg
	Diary No. Date of R & I & Fee	Dy No. 15525: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x1ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	KENACORT A40 triamcinolone acetonide 40mg/1 mL injection, suspension ampoule. TGA approved
	Me-too Status	Dexafort Injection (1ml). Reg. No. 69744 (deos not depict vial or ampule).
	GMP Status	New License
	Remarks of the Evaluator	• You have mentioned injection dosage form. The composition dosage from is injectable suspension.
	Decision: Approved	
1501.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Dixadron 4mg/ml Injection
	Composition	Each 1ml ampoule contains: Dexamethasone Phosphate as Sodium…4mg
	Diary No. Date of R & I & Fee	Dy No. 15511: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Glucocorticoids
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	1x1ml; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Dexamethasone 3.3 mg/ml solution for injection 1 ml ampule. (Each ml of solution for injection contains 4.00 mg of dexamethasone phosphate (as 4.37 mg dexamethasone sodium phosphate) equivalent to 3.32 mg of dexamethasone base). MHRA approved
	Me-too Status	Histopak Injection (1ml). Reg. No. 57655 (deos not depict vial or ampule).
	GMP Status	New License

	Remarks of the Evaluator	•
	Decision: Approved	
Liquid Sterile Ampoule (psychotropic)Section (Human): 07 Molecules/08 Products		
1502.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Dezopam 5mg/ml Injection (2ml)
	Composition	Each ml contains: Diazepam…5mg
	Diary No. Date of R & I & Fee	Dy No. 15607: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's, 25's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Diazepam 5mg/ml Solution for Injection (2ml, 4ml). MHRA approved
	Me-too Status	DIAZEPAM INJECTION 2ml ampule. Reg. No. 01117
	GMP Status	New License
	Remarks of the Evaluator	• Submit updated Form 5 duly signed by all concerned persons. • All signatures shall be in original rather scanned one.
	Decision: Deferred for submission for rectification of shortcomings.	
1503.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Bital 200mg/ml Injection (1ml)
	Composition	Each ml contains: Phenobarbital Sodium…200mg
	Diary No. Date of R & I & Fee	Dy No. 15615: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Barbiturates derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's, 100's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Phenobarbital Sodium 200mg/ml Injection (1ml). MHRA approved
	Me-too Status	P-Bar Injection 1ml ampule. Reg. No. 79731
	GMP Status	New License
	Remarks of the Evaluator	Proof/justification is required about using Sodium edetate.
	Decision: Deferred for justification about using Sodium edetate.	
1504.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Bupnor 0.3mg/ml Injection (1ml)
	Composition	Each ml contains: Buprenorphine HCl Eq. to Buprenorphine…0.3mg
	Diary No. Date of R & I & Fee	Dy No. 15611: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Oripavine derivatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5's, 10's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Temgesic Injection 1ml ampule. MHRA approved
	Me-too Status	Enorfine Injection 1ml. Reg. No. 41528 (deos not show ampule or vial)
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	

1505.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Morine 10mg/ml Injection (1ml)
	Composition	Each ml contains: Morphine Sulphate Pentahydrate Eq. to Morphine Sulphate…10mg
	Diary No. Date of R & I & Fee	Dy No. 15613: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Natural opium alkaloids
	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	Morphine Sulfate Injection BP 10mg in 1ml ampule. MHRA approved
	Me-too Status	Morfscot Injections 10mg. Reg. No. 28300 (deos not show ampule or vial)
	GMP Status	New License
	Remarks of the Evaluator	• The reference and me-too products do not have API in hydrate form. Justify. • In case you prove reference products with API in hydrate form, adjust the quantity of API in master formula (only) as per salt factor.
	Decision: Deferred for: • **Proof proof of International availability of same dosage form with same strength, salt form and same pack size in reference regulatory authority as defined in 275th meeting of the Registration Board, and me-too product with same strength, salt form and same pack size approved by DRAP and adjusmtnet of weight of API in Master Formula, or** • **Revision of API as for abovementioned reference product.**	
1506.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Morine 20mg/ml Injection (1ml)
	Composition	Each ml contains: Morphine Sulphate Pentahydrate Eq. to Morphine Sulphate…20mg
	Diary No. Date of R & I & Fee	Dy No. 15614: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Natural opium alkaloids
	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	Morphine Sulfate Injection BP 20mg in 1ml ampule. MHRA approved
	Me-too Status	Morfscot Injections 10mg. Reg. No. 28301 (deos not show ampule or vial)
	GMP Status	New License
	Remarks of the Evaluator	• The reference and me-too products do not have API in hydrate form. Justify. • In case you prove reference products with API in hydrate form, adjust the quantity of API in master formula (only) as per salt factor.
	Decision: Deferred for: • **Proof proof of International availability of same dosage form with same strength, salt form and same pack size in reference regulatory authority as defined in 275th meeting of the Registration Board, and me-too product with same strength, salt form and same pack size approved by DRAP and adjusmtnet of weight of API in Master Formula, or** • **Revision of API as for abovementioned reference product.**	
1507.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan

	Brand Name + Dosage Form + Strength	Telwin 30mg/ml Injection
	Composition	Each ml contains: Pentazocine as lactate …30mg
	Diary No. Date of R & I & Fee	Dy No. 15581: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Benzomorphan derivatives
	Type of Form	Form-5
	Finished Product Specification	USP (a sterile solution of Pentazocine in Water for Injection, prepared with the aid of Lactic Acid).
	Pack Size & Demanded Price	1x5, 1x10, 25 ampule, 100 ampule; As per SRO
	Approval Status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	AmezocinInjection. Reg. No. 65939 (deos not show ampule or vial)
	GMP Status	New License
	Remarks of the Evaluator	• Clarification is required about the pack size. • The firm revised the salt form in line with the reference product along with submission of Rs. 5000/- fee.
	Decision: Deferred for the following: • **Clarification of pack size.** • **Proof proof of International availability of same dosage form with same strength, salt form and same pack size in reference regulatory authority as defined in 275th meeting of the Registration Board,**	
1508.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Nilbo 10mg/ml Injection
	Composition	Each ml contains: Nalbuphine hydrochloride….10mg
	Diary No. Date of R & I & Fee	Dy No. 15609: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Morphinan derivatives
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufactuer's specifications.
	Pack Size & Demanded Price	2x5 ampule PVC contour cellular package 1 contour cellular in a carton box.
	Approval Status of product in Reference Regulatory Authorities	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved
	Me-too Status	Nalburax Injection. Reg. No. 28830 (deos not show ampule or vial)
	GMP Status	New License
	Remarks of the Evaluator	• Clarification is required about the pack size.
	Decision: Deferred for consideration on its turn as neither Narcotic or Psychotropic as per INCB.	
1509.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Opidol 100mg/2ml Injection
	Composition	Each 2ml ampule contains: Tramadol hydrochloride….100mg
	Diary No. Date of R & I & Fee	Dy No. 15610: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other opioids
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	2mlx10's;, 2mlx30's; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Tramadol 50mg/ml Solution for Injection or Infusion (2ml). MHRA approved
	Me-too Status	Welmadol Injection (2ml). Reg. No. 52629 (deos not show ampule or vial)
	GMP Status	New License

	Remarks of the Evaluator	•
	Decision: Deferred for consideration on its turn as neither Narcotic or Psychotropic as per INCB	
Cream/ointment/Gel Section (Human): 05 Molecules/05 Products		
1510.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Fucilid 15g Cream
	Composition	Each gram contains: Fusidic Acid…20mg
	Diary No. Date of R & I & Fee	Dy No. 15588: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Other antibiotics for topical use
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	15g, 30g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Fusidic Acid 2% Cream. MHRA approved
	Me-too Status	Tica-H Cream. Reg. No. 54358
	GMP Status	New License
	Remarks of the Evaluator	•
	Decision: Approved	
1511.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Fucilid-H Cream
	Composition	Each gram contains: Fusidic Acid…20mg Hydrocortisone Acetate…10mg
	Diary No. Date of R & I & Fee	Dy No. 15587: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Corticosteroids + Fusidic acid (not in ATC)
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	15g, 30g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Fucidin H Cream. MHRA approved
	Me-too Status	Dercid -H Cream. Reg. No. 24166
	GMP Status	New License
	Remarks of the Evaluator	Submit updated Form 5 duly signed by all concerned persons
	Decision: Deferred for submission of updated Form 5.	
1512.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Areeba Trim Cream
	Composition	Each gram contains: Fluocinolone Acetonide…0.1mg Hydroquinone…40mg Tretinoin…0.5mg
	Diary No. Date of R & I & Fee	Dy No. 15586: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	30g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	TRI-LUMA® (fluocinolone acetonide, hydroquinone, and tretinoin) cream, 0.01%, 4%, 0.05% for topical use by Galderma Labs LP. **US-FDA** approved
	Me-too Status	Trimelasin Cream by Valor Pharmaceuticals. R.No. 31104
	GMP Status	New License
	Remarks of the Evaluator	•

	Decision: Approved with innovator's specifications.	
1513.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Trima-H Cream
	Composition	Each gram contains: Clotrimazole…10mg Hydrocortisone as Acetate…10mg
	Diary No. Date of R & I & Fee	Dy No. 15584: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack Size & Demanded Price	30g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	Canesten HC Cream. MHRA approved
	Me-too Status	Aquazole Cream 10gm by Martin Dow. Reg. No. 67931 (contains Hydrocortisone Acetate instead of Hydrocortisone as Acetate)
	GMP Status	New License
	Remarks of the Evaluator	The firm revised hydrocortisone to hycdrocortisone acetate in master Formula and adjusted its quantity as per salt factor.
	Decision: Approved with innovator's specifications	
1514.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Pendic Gel 1%
	Composition	Each gram contains: Diclofenac diethylamine 11.6 mg eq. to Diclofenac sodium…..10mg
	Diary No. Date of R & I & Fee	Dy No. 15585: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids 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	VOLTAREN OSTEO GEL diclofenac diethylamine 11.6mg/g (1.16%) tube. **USFDA** approved. With no equivalency.
	Me-too Status	Dicmaf 1% Gel. With label claim "each gram contains: Diclofenac Diethylamine 11.6 mg eq. to Diclofenac Sodium.10 mg". Reg No. 79899
	GMP Status	New License
	Remarks of the Evaluator	The compostions depict that the product is emulsion. Clarify.
	Decision: Deferred for clarification about the compositions.	

Case No. 03: Registration Applications of Newly Granted DML or New Section (Veterinary).

a. Deferred Cases

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 generics (08 products).		
1515.	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: Neomycin sulphate…… 400mg Streptomycin sulphate….400mg Sulfaguanidine……4g Kaolin……..4g Pectin……..400mg Bismuth subnitrate……2g 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 did not replied. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • For submission of complete Form-5 • The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section
	Evaluation by PEC	• The firm removed overage • Updated Form 5 submitted • The firm has claimed innovator's specifications • 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 consideration on its turn.	

1516.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Diarin Oral Powder
	Composition	Each 28grams contain: Neomycin sulphate…… 0.538g Streptomycin sulphate….0.676g Sulfaguanidine……5g Phthalyl sulphathiazole…….1.5g Riboflavin……..0.1g Nicotinamide……0.5g
	Diary No. Date of R& I & fee	Dy No. 40582: 06.12.2018 PKR 20,000/-: 06.12.2018
	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	As recorded for above application
	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. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm • Justification on scientific basis for addition of overage in master formulation. • For submission of complete Form-5 • The firm has claimed the product on priority for Oral Powder (penicillin) Veterinary. However, the product is not related to the said section
	Evaluation by PEC	• The firm removed overage • Updated Form 5 submitted • The firm has claimed innovator's specifications • 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 consideration on its turn	
1517.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Listin-Hi WSP
	Composition	Each gram contains:

		Amoxicillin trihydrate…… 200mg Lincomycin base….88mg Spectinomycin base……88mg Vitamin E Acetate……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	As recorded for above application
	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. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • The me-too product contains Lincomycin Base; however, the firm has revised Lincomycin Base to Lincomycin as HCl without submission of any fee. • 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.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • For submission of complete Form-5 • Revision of formulation in line with reference product along approved by DRAP with submission of fee
	Evaluation by PEC	• The firm removed overage • Updated Form 5 submitted • The firm has claimed innovator's specifications • The firm again revised lincomycin HCl to Lincomycin base. • The firm revised Vitamin E to Vitamin E acetate with submission of fee Rs. 5000/- (Dy. No. 5552; 08.05.2019).
	Decision: Approved	
1518.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Phenox Plus WSP
	Composition	Each gram contains: 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	As recorded for above application
	Remarks of the Evaluator.	• Undertakings have not been signed. • Reference (Pharmacopeia / innovator / manufacturer) for finished product specifications is required. • Submit clear stepwise manufacturing outlines. • Complete finished product specifications and testing method are needed. • Details of environmental control processing including waste disposal management. • Proof of me-too product (name and registration number) with same dosage form, same salt form and same strength is required • Justification for overage is required. • Signature at the beginning of Form 5 is missing. • The firm has mentioned the word flavor. The name of flavor that will be used in the product is required.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Justification on scientific basis for addition of overage in master formulation. • For submission of complete Form-5 • Submision of clear stepwise manufacturing outlines and testing methods.
	Evaluation by PEC	• The firm removed overage. • Updated Form 5 submitted. • Submit clear stepwise manufacturing outlines. • **Me-too status could not be confirmed** • The firm has mentioned the word flavor. The name of flavor that will be used in the product is required.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Submit clear stepwise manufacturing outlines.** • **The name of flavor that will be used in the product is required.**	
1519.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Klavimox WSP
	Composition	Each 100 grams contain: Amoxicillin as trihydrate…….16g 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
	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. No. 074026
	GMP status	As recorded for above application
	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. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management. • 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. • Correction of 'clavulanic acid as potassium' to 'potassium clavulanate' is required in Master Formula. • The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee. • Available in USP, wherein the monograph is for "for oral suspension'.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Correction of amoxicillin as trihydrate to amoxicillin trihydrate in Master Formula is required. • Details of environmental control processing including waste disposal management is needed. • 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. • Correction of 'clavulanic acid as potassium' to 'potassium clavulanate' is required in Master Formula. • The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee.
	Evaluation by PEC	• The firm removed overage. • Updated Form 5 submitted. • The firm has claimed innovator's specifications • The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee. • 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. • Available in USP, wherein the monograph is for "for oral

		suspension'.
	Decision: Deferred for the following: • **Submission of fee for revision of salt form.** • **Submission of correct dosage** • **Clairifaction about the dosage form.**	
1520.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Avipen 325 WSP
	Composition	Each gram contains: 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 Reference Regulatory Authorities.	NA
	Me-too status	PHENOXYPEN WATER SOLUBLE POWDER. Reg. No. 081303
	GMP status	As recorded for above application
	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. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management are missing. • 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.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management are missing. • 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.
	Evaluation by PEC	• The firm removed overage. • Updated Form 5 submitted. • The firm has claimed innovator's specifications • The me-too product contains phenoxymethylpenicillin (293mg/g) eq. to potassium phenoxymethylpenicillin (325mg/g). The firm was asked for correction in label claim (Form 5 only) along with submission of applicable fee. The firm submitted Rs. 5000/- fee but revision of label claim is required.
	Decision: Deferred for revision of label claim.	
1521.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Avigrow 100 WSP
	Composition	Each kg contains: Procaine penicillin…….12g Streptomycin sulfate ……36g 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	As recorded for above application
	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. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management. • 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.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management are missing.

		• 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.
	Evaluation by PEC	• The firm removed overage. • Updated Form 5 submitted. • The firm has claimed innovator's specifications • The firm revised 'streptomycin' to 'streptomycin sulphate'. The firm was asked to submit applicable fee. Then firm again changed streptomycin sulphate to streptomycin. • The firm has now revised streptomycin to streptomycin sulfate along with submission of Rs. 5000/- fee. • The firm submitted details of environmental control processing.
	Decision: Approved with innovator's specifications	
1522.	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: Amoxicillin trihydrate…….20g Lincomycin…….8.8g 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	As recorded for above application
	Remarks of the Evaluator.	• Undertaking at the end of form 5 is missing. • The me-too product contains amoxicillin trihydrate. The firm has mentioned amoxicillin trihydrate. • Details of environmental control processing including waste disposal management. • Justification for overage is required. • The firm has mentioned the word flavor. The name of flavor that will be used in the product is required.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • Undertaking at the end of form 5 is missing. • The me-too product contains amoxicillin trihydrate. The firm has mentioned amoxicillin as trihydrate. • Details of environmental control processing including waste disposal management. • The firm has mentioned the word flavor. The name of flavor that will be used in the product is required.
	Evaluation by PEC	• The firm removed overage and flavor. • Updated Form 5 submitted. • The firm revised amoxicillin as trihydrate to amoxicillin trihydrate. • The firm submitted details of environmental control

		processing. • The firm removed the flavor form the compositions.
	Decision: Approved with innovator's spcifications	

Case No. 05: Registration Applications of Categories to be Considered on Priority.

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

1523.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals, Factory Plot # 122, Block B, Phase V, Industrial Estate, Hattar, District Haripur, Pakistan
	Brand Name +Dosage Form + Strength	Nelfi 250mg tablet
	Composition	Each film-coated tablet contains: Nelfinavir as Mesylate…..250mg
	Diary No. Date of R& I & fee	Dy No. 39451: 30.11.2018 PKR 20,000/-: 30.11.2018
	Pharmacological Group	Protease inhibitors
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	VIRACEPT® (nelfinavir mesylate) film-coated Tablets, for oral use USFDA approved
	Me-too status	NELFIN–250 Tablets. Reg. No.41115
	GMP status	The firm was inspected on 04.09.2018 & 26.09.2018 with the conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	• The firm revised Nelfinavir Mesylate to Nelfinavir as Mesylate in Form 5 without any fee.
	Decision: Deferred for submission of fee	

1524.	Name and address of manufacturer / Applicant	Aulton Pharmaceutical, Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar Pakistan
	Brand Name +Dosage Form + Strength	Leflunomalt 10mg tablet
	Composition	Each film-coated tablet contains: Leflunomide…… 10mg
	Diary No. Date of R& I & fee	Dy No. 39448: 30.11.2018 PKR 20,000/-: 30.11.2018
	Pharmacological Group	Immunosuppressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Leflunomide 10 mg Film-coated Tablets Approved by MHRA
	Me-too status	Zefora Tablets 10mg. Reg. No.66488
	GMP status	The firm was last inspected on 13.02.2018, wherein it was concluded that "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.	• The firm was asked to provide clear and complete manufacturing outlines mentioning the addition/mixing of each component of the formulation including APIs. The firm submitted inomplete having instructions/precautionary measures.
	Decision: Deferred for submission of complete manufacturing outlines.	

b. Export facilitation

Following three cases were received from section I & V-I vide letter No. F.1-9/2013-Reg-I dated 19.02.2019. According to the contents of the letter the firm has claimed two molecules (03 products) to be considered on priority basis in lieu of export facilitation.

1525.	Name and address of manufacturer / Applicant	Selmore Pharmaceuticals (Pvt.) Ltd., 36 Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Triox Drench
	Composition	Each 100 ml contain: Oxfendazole……..2.265g Triclabendazole…….8.50g
	Diary No. Date of R& I & fee	Dy No. 32735: 02.10.2018 PKR 20,000/-: 02.10.2018
	Pharmacological Group	Other antitrematodal agents + Oxfendazole (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	100ml, 500ml, 1000ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	VORCID SUSPENSION. Reg. No. 063563
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018, wherein renewal of DML: was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifcation	
1526.	Name and address of manufacturer / Applicant	Selmore Pharmaceuticals (Pvt.) Ltd., 36 Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Amoxygent Forte IM Injection 50ml
	Composition	Each ml contains: Amoxicillin trihydrate……...150mg Gentamycin sulfate eq. to Gentamycin……40mg
	Diary No. Date of R& I & fee	Dy No. 35898: 30.10.2018 PKR 20,000/-: 29.10.2018
	Pharmacological Group	Penicillins with extended spectrum + aminoglycoside (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	GENTAMOX INJECTION (100ml). Reg. No. 80160
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018, wherein renewal of DML: was recommended.
	Remarks of the Evaluator.	• The registration board in its meeting 287th meeting approved 100ml on the basis of 50ml.
	Decision: Approved with innovator's specifications	
1527.	Name and address of manufacturer / Applicant	Selmore Pharmaceuticals (Pvt.) Ltd., 36 Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Amoxygent Forte IM Injection 100ml
	Composition	Each ml contains: Amoxicillin trihydrate……...150mg Gentamycin sulfate eq. to Gentamycin……40mg
	Diary No. Date of R& I & fee	Dy No. 35900: 30.10.2018 PKR 20,000/-: 29.10.2018

	Pharmacological Group	Penicillins with extended spectrum + aminoglycoside (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	GENTAMOX INJECTION (100ml). Reg. No. 80160
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018, wherein renewal of DML: was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved	

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

i. Human

1528.	Name and address of Applicant	Aster Life Sciences 32-Babar Block, New Garden Town, Lahore
	Detail of Drug Sale License	No. 05-352-0065-013801D, valid till 29.11.2019 Address: 32-Babar Block, New Garden Town, Lahore
	Name and address of Manufacturer	Panacea Biotec Limited, Vill. Malpur, Baddi, Distt. Solan, Himachal Pradesh-173205, India
	Name and address of marketing authorization holder	M/s Panacea Biotech Ltd., Village Malpur, Baddi, Distt. Solan-173205, Himachal Pradesh, India
	Name of exporting country	India
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No. 25111: 19.07.2018
	Fee including differential fee	PKR 50,000/-: 19.07.2018
	Brand Name +Dosage Form + Strength	PacliAll Lyophilzed Powder for Injectable Suspension
	Composition	Each vial contains: Paclitaxel USP…..100mg Human Albumin USP……..900mg
	Pharmacological Group	Taxanes
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities.	ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension, albumin-bound). Label claim; Each single-use vial contains 100mg of paclitaxel (bound to human albumin) and approximately 900 mg of human albumin (containing sodium caprylate and sodium acetyltryptophanate) USFDA approved with box warning.
	Me-too status	ONCOTAXEL 100MG. Reg. No. 78156 (does not depict protein bounding).
	Detail of certificate attached	• Original, legalized COPP, valid till 11.02.2020 issued by State Drug Controller Distt. Solan Himachal Pradesh is attached. • Original, legalized FSC, valid till 10.10.2020 issued by State Drug Controller Distt. Solan Himachal Pradesh is attached. • Original legalized GMP certificate valid until 11.02.2020 issued by Health and Family Welfare Department, Himachal Pradesh Baddi Distt. Solan is attached. • Original legalized Sole agent letter is provided which is valid till 31.03.2021.
	Remarks of the Evaluator.	• It has been mentioned in the COPP, SmPC and composition that the product contains Chloroform and Ethanol. Upon clarification, the firm submitted that these solvents are subsequently removed

		during the process. The level of these solvent in final drug product are controlled to concentrations much below the allowable limits as per ICH Q3C guidelines. • The label claim of reference product is "Each single-use vial contains 100mg of paclitaxel (bound to human albumin) and approximately 900mg of human albumin (containing sodium caprylate and sodium acetyltryptophanate)". However, the applied product has label claim "Each vial contains 100 mg of paclitaxel and 900mg of human albumin USP". • In the reference product, human albumin has been stabilized by sodium caprylate and sodium acetyltryptophanate. Clarification was asked for such stabilization of your product. The firm submitted that the albumin contains such stabilizing agents. The firm submitted COA of albumin from CSL Behring, Switzerland, mentioning sodium caprylate and sodium acetyltryptophan.
	Decision: Deferred for further delibration	

Evaluator PEC-XII

Case no. 01 Registration Applications for Local Manufacturing of (Human) Drugs.

a. Deferred cases

1529.	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
	Composition	Form-5 Dy.No 5423 dated 14-02-2018 Rs. 20,000/- 14-02-2018
	Diary No. Date of R& I & fee	Each 10ml Contains: Sodium Alginate…500mg Sodium Bicarbonate…267mg 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 Company is found complying GMP
	Remarks of the Evaluator.	Evidence of Atomic absorption apparatus not submitted by firm
	Decision of previous meeting of RB	Deferred for confirmation of availability of atomic absorption spectrophotometer. (M-288)
	Evaluation by PEC	• Firm has submitted panel inspection report dated 06-08-2018. The report states that the quality control lab of the firm has atomic absorption spectrophotometer. To perform routine tests/ analysis.
	Decision: Approved.	
1530.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Vepridone 1mg ODT Tablet
	Composition	Form-5 Dy.No 1055 dated 08-01-2018 Rs. 20,000 08-01-2018
	Diary No. Date of R& I & fee	Each Oraly Disintegrating Tablet Contains: Risperidone…1mg
	Pharmacological Group	Other antipsychotics
	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.	RISPERDAL Quicklet 1 mg orodispersible tablets by M/s Janssen-Cilag Ltd (MHRA Approved)
	Me-too status	Wizen Flash Tablets 1mg by M/s Werrick Pharmaceuticals (Reg#034340)
	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 of previous meeting of RB	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. (M-287)
	Evaluation by PEC	• Firm has submitted panel inspection report dated 29-03-2019 for GMP compliance. The report states that panel was of opinion that the firm was operating at satisfactory level of GMP compliance.
	Decision: Approved.	
1531.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Vepridone 2mg ODT Tablet
	Composition	Form-5 Dy.No 1056 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Diary No. Date of R& I & fee	Each Oraly Disintegrating Tablet Contains: Risperidone…2mg
	Pharmacological Group	Other antipsychotics
	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.	RISPERDAL Quicklet 2 mg orodispersible tablets by M/s Janssen-Cilag Ltd (MHRA Approved)
	Me-too status	Wizen Flash Tablets 2mg by M/s Werrick Pharmaceuticals (Reg#034341)
	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 of previous meeting of RB	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. (M-287)
	Evaluation by PEC	• Firm has submitted panel inspection report dated 29-03-2019 for GMP compliance. The report states that panel was of opinion that the firm was operating at satisfactory level of GMP compliance.
	Decision: Approved.	
1532.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Vepridone 3mg ODT Tablet
	Composition	Form-5 Dy.No 1057 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Diary No. Date of R& I & fee	Each Oraly Disintegrating Tablet Contains: Risperidone…3mg
	Pharmacological Group	Other antipsychotics
	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.	RISPERDAL Quicklet 3 mg orodispersible tablets by M/s Janssen-Cilag Ltd (MHRA Approved)

	Me-too status	Wizen Flash Tablets 3mg by M/s Werrick Pharmaceuticals (Reg#034342)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision of previous meeting of RB	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. (M-287)
	Evaluation by PEC	• Firm has submitted panel inspection report dated 29-03-2019 for GMP compliance. The report states that panel was of opinion that the firm was operating at satisfactory level of GMP compliance.
	Decision: Approved.	
1533.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Vepridone 4mg ODT Tablet
	Composition	Form-5 Dy.No 1058 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Diary No. Date of R& I & fee	Each Oraly Disintegrating Tablet Contains: Risperidone…4mg
	Pharmacological Group	Other antipsychotics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	120's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL Quicklet 4 mg orodispersible tablets by M/s Janssen-Cilag Ltd (MHRA Approved)
	Me-too status	Wizen Flash Tablets 4mg by M/s Werrick Pharmaceuticals (Reg#034343)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	
	Decision of previous meeting of RB	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. (M-287)
	Evaluation by PEC	• Firm has submitted panel inspection report dated 29-03-2019 for GMP compliance. The report states that panel was of opinion that the firm was operating at satisfactory level of GMP compliance.
	Decision: Approved.	
1534.	Name and address of manufacturer / Applicant	M/s Rogen Pharmaceuticals (Pvt.) Ltd, Plot #: 30, Street No. S-4, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Letrogen 1mg Tablets
	Composition	Dy No. 30025: 06-09-2018 PKR 20,000/-: 06-09-2018
	Diary No. Date of R& I & fee	Each tablet contains: Letrozole …2.5mg
	Pharmacological Group	Non-Steroidal aromatase inhibitor
	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.	FEMARA letrozole 2.5mg coated tablet by Novartis Pharmaceuticals Australia Pty Ltd (TGA Approved)
	Me-too status	Femara 2.5mg Tablet by Novartis (Reg. No. 021129)
	GMP status	7-9-2017 renewal of DML and grant of additional section. Panel recommends renewal of DML & grant of additional section.
	Remarks of the Evaluator.	Firm has applied as uncoated tablet whereas approved formulation in RRA is film coated.
	Decision of previous meeting of RB	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of

		formulation (M-287)
	Evaluation by PEC	Firm has revised formulation as per reference product along with submission of 5,000 fee dated 01-01-2019 (Challan#0550130). The revised formulation submitted by the firm is as: Each film coated tablet contains: Letrozole …2.5mg
	Decision: Approved.	
1535.	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	Elpha Tablet 2mg
	Composition	Dy No. 8179: 10-7-2017 PKR 20,000/-: 10-07-2017
	Diary No. Date of R& I & fee	Each film coated tablet contains: Melphalan (as hydrochloride)……..2mg
	Pharmacological Group	Alkylating agent
	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.	Alkeran Tablet by Apotex Inc. (USFDA Approved)
	Me-too status	Alkaran tablet by GSK
	GMP status	30-03-2017: Grant of Additional Sections Panel recommends grant of Additional Sections
	Remarks of the Evaluator.	● Justify the formulation containing melphalan (as hydrochloride) since the reference product contains melphalan only. ● After communication of above observation vide letter no. F.1-1/2017/PEC-DRAP dated 19-04-2018, the firm has submitted revised Form 5 along with composition and master formulation, details of which are as under: "Each tablet contains: Melphalan …… 2mg"
	Decision of previous meeting of RB	Deferred for submission of fee for revision of formulation. (M-282)
	Evaluation by PEC	Firm has revised formulation as per reference product along with submission of 5,000 fee dated 29-04-2019 (Challan#1930971). The revised formulation submitted by the firm is as: "Each tablet contains: Melphalan …… 2mg"
	Decision: Registration Board approved registration of product 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.	
1536.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals, Plot #122 Phase 5, Block B, Hattar. Contract manufactured by: M/s Weatherfold Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Cypomark 2mg/35mcg Tablets
	Diary No. Date of R& I & fee	Form-5 Dy.No 1463 dated 10-01-2018 Rs. 50,000/- 10-01-2018
	Composition	Each Film Coated Tablet Contains: Cyproterone Acetate…2mg Ethinyloestradiol…35mcg
	Pharmacological Group	Anti-androgen/ Oestrogen (Anti-Acne Preps)
	Type of Form	Form – 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Co-Cyprindiol 2000/35 Coated Tablets by M/s Strandhaven

	Reference Regulatory Authorities.	Limited (MHRA approved)
	Me-too status	Diane-35 Tablets by M/s ALI GOHAR & CO (Reg#011467)
	GMP status	**Welmark Pharmaceuticals:** 04-09-2018 & 26-09-2018 Keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML **Weatherfold Pharmaceuticals:** Last GMP Inspection conducted on 15-09-2017 concluded that overall the firm was GMP compliant as per DRAP guidelines
	Remarks of the Evaluator.	• Firm has does not have Tablet (Hormone) section.
	Decision of previous meeting of RB	Deferred for evidence of approval of required manufacturing facility of "Tablet (Hormone) section" by Central Licensing Board. (M-287)
	Evaluation by PEC	• Firm has submitted that it wants to revise the contract to M/s Wnsfield Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Hattar Industrial Estate, Hattar. • Firm has submitted contract copy (on stamp paper) between contract giver i.e.: M/s Welmark Pharmaceuticals. And contract acceptor M/s Wnsfield Pharmaceuticals dated 19-12-2018. • Products mentioned in contract are: i. Cypomark 2mg/35mcg Tablets (Cyproterone Acetatev+Ethinyloestradiol) ii. Norcewel 5mg Tablet (Norethisterone Acetate) iii. Dyfowel 10mg Tablet (Dydrogesterone) iv. Levonorgesterel 750mcg Tablet • M/s Wnsfield Pharmaceuticals has Tablet (Steroidal hormone) section approved by CLB in its 267th meeting held on 31-12-2018. • Last GMP inspection of M/s Wnsfield Pharmaceuticals conducted on 18-01-2018, and the report concludes that keeping in view of overall GMP compliance, the panel recommend the Renewal of DML.
	Decision: Approved with innovator's specification for contract manufacturing by M/s Wnsfield Pharmaceuticals, Hattar. The Board further advised the manufacturer to get approval for "Tablet (steroidal hormone) section" from Licensing Division before issuance of Registration letter.	
1537.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals, Plot #122 Phase 5, Block B, Hattar Contract manufactured by: M/s Weatherfold Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Norcewel 5mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 1464 dated 10-01-2018 Rs. 50,000/- 10-01-2018
	Composition	Each Tablet Contains: Norethisterone Acetate…5mg
	Pharmacological Group	Progestogen
	Type of Form	Form – 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Norethisterone 5mg Tablets by M/s Wockhardt UK Ltd , (MHRA approved)
	Me-too status	Feminor 5mg tablet by M/s Wilson (Reg#011160)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Firm has does not have Tablet (Hormone) section.
	Decision of previous meeting of RB	Deferred for evidence of approval of required manufacturing facility of "Tablet (Hormone) section" by Central Licensing Board. (M-287)
	Evaluation by PEC	• Firm has submitted that it wants to revise the contract to

		M/s Wnsfield Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Hattar Industrial Estate, Hattar. • Firm has submitted contract copy (on stamp paper) between contract giver i.e.: M/s Welmark Pharmaceuticals. And contract acceptor M/s Wnsfield Pharmaceuticals dated 19-12-2018. • Products mentioned in contract are: i. Cypomark 2mg/35mcg Tablets (Cyproterone Acetatev+Ethinyloestradiol) ii. Norcewel 5mg Tablet (Norethisterone Acetate) iii. Dyfowel 10mg Tablet (Dydrogesterone) iv. Levonorgesterel 750mcg Tablet • M/s Wnsfield Pharmaceuticals has Tablet (Steroidal hormone) section approved by CLB in its 267th meeting held on 31-12-2018. • Last GMP inspection of M/s Wnsfield Pharmaceuticals conducted on 18-01-2018, and the report concludes that keeping in view of overall GMP compliance, the panel recommend the Renewal of DML.
	Decision: Approved with BP specification for contract manufacturing by M/s Wnsfield Pharmaceuticals, Hattar. The Board further advised the manufacturer to get approval for "Tablet (steroidal hormone) section" from Licensing Division before issuance of Registration letter.	
1538.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals, Plot #122 Phase 5, Block B, Hattar Contract manufactured by: M/s Weatherfold Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Dyfowel 10mg Tablet
	Diary No. Date of R& I & fee	Form-5 Dy.No 1457 dated 10-01-2018 Rs. 50,000/- 10-01-2018
	Composition	Each Film Coated Tablet Contains: Dydrogesterone…10mg
	Pharmacological Group	Progestogen
	Type of Form	Form – 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duphaston 10 mg film-coated tablet by M/s Mylan Medical SAS , (ANSM approved)
	Me-too status	Duphaston 10 mg tablet by M/s Abbott(Reg#006654)
	GMP status	As recorded for above application
	Remarks of the Evaluator.	• Firm has does not have Tablet (Hormone) section.
	Decision of previous meeting of RB	Deferred for evidence of approval of required manufacturing facility of "Tablet (Hormone) section" by Central Licensing Board. (M-287)
	Evaluation by PEC	• Firm has submitted that it wants to revise the contract to M/s Wnsfield Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Hattar Industrial Estate, Hattar. • Firm has submitted contract copy (on stamp paper) between contract giver i.e.: M/s Welmark Pharmaceuticals. And contract acceptor M/s Wnsfield Pharmaceuticals dated 19-12-2018. • Products mentioned in contract are: i. Cypomark 2mg/35mcg Tablets (Cyproterone Acetatev+Ethinyloestradiol) ii. Norcewel 5mg Tablet (Norethisterone Acetate) iii. Dyfowel 10mg Tablet (Dydrogesterone) iv. Levonorgesterel 750mcg Tablet • M/s Wnsfield Pharmaceuticals has Tablet (Steroidal hormone) section approved by CLB in its 267th meeting

		held on 31-12-2018. • Last GMP inspection of M/s Wnsfield Pharmaceuticals conducted on 18-01-2018, and the report concludes that keeping in view of overall GMP compliance, the panel recommend the Renewal of DML.
	Decision: Approved with BP specification for contract manufacturing by M/s Wnsfield Pharmaceuticals, Hattar. The Board further advised the manufacturer to get approval for "Tablet (steroidal hormone) section" from Licensing Division before issuance of Registration letter.	
1539.	Name and address of manufacturer / Applicant	M/s Pacific Pharmaceuticals Ltd, 30-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Exestane 25mg Tablets
	Diary No. Date of R& I & fee	Diary No:10938, 26/03/2018, Rs. 20,000/-
	Composition	Each film-coated tablet contains: Exemestane…25mg
	Pharmacological Group	Aromatase inhibitors (Steroidal)
	Type of Form	Form – 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	3x5's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aromasin 25 mg coated tablets by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Ph&T Exemestane 25mg Coated Tablets by M/s Mehran International (Reg#078122)
	GMP status	07-11-2017. Panel recommends grant of Additional sections
	Remarks of the Evaluator.	
	Decision of previous meeting of RB	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. **(M-281)** Deferred for clarification whether the applied product is hormone or otherwise. **(M-286)**
	Evaluation by PEC	• Firm has submitted that the applied product is steroidal aromatase inhibitor and it was confirmed as well.
	Decision: Deferred for confirmation of concerned section	
1540.	Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 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/- 25-01-2019
	Composition	Each 5ml Contains: 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 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 of previous meeting of RB	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. **(M-288)**
	Evaluation by PEC	• Firm has revised the formulation as follows:

		Each 5ml Contains: Fosfomycin (as calcium) …250mg Alongwith form 5 and master formulation • Firm has submitted fee challan of Rs.5,000/- (Challan#812309) Dated 11-02-2019
	Decision: Approved.	
1541.	Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt) Ltd. 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/- 25-01-2019
	Composition	Each film Coated Tablet Contains: 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
	Me-too status	Elgin 500 mcg tablet of M/s Novartis Pharma (Pvt) Limited (Reg. # 032638)
	GMP status	13-04-2018; Grant of DML.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 of previous meeting of RB	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. **(M-288)**
	Evaluation by PEC	• Firm has revised the formulation as follows: Each sugar Coated Tablet Contains: Mecobalamin…500mcg Alongwith form 5 and master formulation • Firm has submitted fee challan of Rs. 5000/- (Challan#817188) Dated 11-02-2019
	Decision: Approved.	

Case No. 02: Registration Applications of Newly Granted DML or New Section (Human).

a. New DML

M/s Cure Laboratories (Pvt) Ltd., Rawalpindi (New Licence)

CLB in its 269th meeting held on 26th Feb 2019 has considered and granted the Drug Manufacturing License (DML) to M/s Cure Laboratories (Pvt) Ltd **by way of formulation** and granted (03) new section to the firm. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

Sr.No	Section	No. of Products	No of Molecules
1	Capsule Section (Cephalosporin)	17	09
2	Dry Powder Suspension (Cephalosporin) Section	19	10
3	Dry Powder Vial (Sterile) (Cephalosporin) Section	36	10

Cephalosporin Capsule Section 17 Products/09 Molecules		
1542.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	Caflor 250mg Capsule
	Composition	Each capsule contains:- Cefaclor (as monohydrate)....250mg
	Diary No, Date of R & I & fee	Dy.No 11187 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin

	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefaclor 250mg Capsules by M/s Ranbaxy (UK) Limited (MHRA Approved)
	Me-too status	Faceclor 250mg Capsule by M/s City Karachi (Reg#070600)
	GMP Status	19-02-2019 &22-02-2019 Grant of DML Panel unanimously recommended grant of DML
	Remarks of the Evaluator	
	Decision: Approved.	
1543.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd.Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Caflor 500mg Capsule
	Composition	Each capsule contains:- Cefaclor (as monohydrate)...500mg
	Diary No, Date of R & I & fee	Dy.No 11188 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefaclor Capsules 500mg by M/s Strides Pharma UK Ltd (MHRA Approved)
	Me-too status	Faceclor 500mg Capsule by M/s City Karachi (Reg#070601)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1544.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Roxikef 250mg Capsule
	Composition	Each capsule contains:- Cefadroxil (as monohydrate).....250mg
	Diary No, Date of R & I & fee	Dy.No 11178 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12s, As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Oradrox Capsules 250mg M/s Biorex Pharmaceutical (Reg#031876)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1545.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd, Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Roxikef 500mg Capsule
	Composition	Each capsule contains:- Cefadroxil (as monohydrate).....500mg
	Diary No, Date of R & I & fee	Dy.No 11179 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's /As per SRO
	Approval Status of product in Reference	Cefadroxil 500 mg capsules, hard by M/s Alkaloid-INT d.o.o.

	Regulatory Authorities.	(MHRA Approved)
	Me-too status	Evacef 500mg Capsules by M/s Highnoon Laboratories (Reg#009141)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1546.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Roxikef 1000mg Capsule
	Composition	Each capsule contains:- Cefadroxil (as monohydrate).....1000mg
	Diary No, Date of R & I & fee	Dy.No 11180 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12s , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Safedroxil 1g Capsule M/s Safe Pharmaceuticals (Reg#048856)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1547.	Name and address of Manufacturer / Applicant	**M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.**
	Brand Name + Dosage Form + Strength	**Poxime 100mg Capsule**
	Composition	Each capsule contains: Cefpodoxime (as proxetil)…100mg
	Diary No, Date of R & I & fee	Dy.No 11189 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	12s / As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Qink Capsules 100mg M/s Wilshire (Reg#036255)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	• Approval Status of product in Reference Regulatory Authorities not confirmed. • Master formulation submitted by the firm is of another product.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.** • **Submission of master formulation for applied product.**	
1548.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fixikef 200mg Capsule
	Composition	Each capsule contains:- Cefixime (as trihydrate).....200mg
	Diary No, Date of R & I & fee	Dy.No 11185 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	5s , As per SRO

	Approval Status of product in Reference Regulatory Authorities.	Spain approved
	Me-too status	Cefix Capsules 200mg M/s Biosynth (Reg#030249)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1549.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fixikef 400mg Capsule
	Composition	Each capsule contains:- Cefixime (as trihydrate).....400mg
	Diary No, Date of R & I & fee	Dy.No 11186 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	5's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Suprax 400 mg capsules by Lupin Pharma (USFDA Approved)
	Me-too status	Cefiget Capsule 400 mg by Getz Pharma (Reg#045118)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1550.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Velofex 250mg Capsule
	Composition	Each capsule contains:- Cephradine....250mg
	Diary No, Date of R & I & fee	Dy.No 11176 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefradine 250mg Capsules by M/s Athlone Pharmaceuticals Limited (MHRA Approved)
	Me-too status	Zasinol 250mg capsule byM/s Martin Dow (Reg#080643)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1551.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Velofex 500mg Capsule
	Composition	Each capsule contains:- Cephradine.....500mg
	Diary No, Date of R & I & fee	Dy.No 11177 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	12's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefradine 500mg Capsules by M/s Athlone Pharmaceuticals Limited (MHRA Approved)
	Me-too status	Dinar 500mg capsule byM/s Baxter Pharma (Reg#084548)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1552.	Name and address of Manufacturer /	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No.

	Applicant	NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Rinidef 100mg Capsule
	Composition	Each Capsule Contains: Cefdinir…100mg
	Diary No, Date of R & I & fee	Dy.No 11181 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	6s /, As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefzon capsule 100 mg by M/s Astellas Pharma Inc. (PMDA Japan Approved)
	Me-too status	Cefnir 100mg Capsule by M/s Barret Hodgson (Reg#023931)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1553.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Rinidef 300mg Capsule
	Composition	Each Capsule Contains: Cefdinir…300mg
	Diary No, Date of R & I & fee	Dy.No 11182 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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.	Cefdinir 300mg Capsule by M/s Sandoz (USFDA approved)
	Me-too status	Zaply 300mg capsule by Wilshire/Horizon (Reg#053638)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1554.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Curakef 250mg Capsule
	Composition	Each capsule contains:- Cephalexin (as monohydrate).....250mg
	Diary No, Date of R & I & fee	Dy.No 11191 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x6's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefalexin 250 mg Capsules, HARD by M/s Athlone Pharmaceuticals Limited (MHRA Approved)
	Me-too status	Xtab-250 Capsule by M/s Wellborne Pharmachem and biological (Reg#081747)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1555.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Curakef 500mg Capsule
	Composition	Each Capsule Contains: Cephalexin (as monohydrate)…500mg
	Diary No, Date of R & I & fee	Dy.No 11192 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	2x6's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefalexin 500 mg Capsules by M/s Alkem Pharma GmbH (MHRA Approved)
	Me-too status	Ceporex 500mg Capsule by M/s GSK (Reg#005641)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1556.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 250mg Capsule
	Composition	Each hard gelatin Capsule contains: Cefuroxime (as axetil) ...250mg
	Diary No, Date of R & I & fee	Dy.No 11183 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	12s /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Trucef capsule by M/s Synchro Pharma (Reg#048978)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1557.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 500mg Capsule
	Composition	Each hard gelatin Capsule contains: Cefuroxime (as axetil) ...500mg
	Diary No, Date of R & I & fee	Dy.No 11184 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	12s /, As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Trucef capsule by M/s Synchro Pharma (Reg#048978)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	• Approval Status of product in Reference Regulatory Authorities not confirmed. • Master formulation submitted by the firm is of another product.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.** • **Submission of master formulation for applied product.**	
1558.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Bitafen 400mg Capsule
	Composition	Each Capsule Contains: Ceftibuten (as dihydrate)…400mg
	Diary No, Date of R & I & fee	Dy.No 11190 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	Type of Form	Form-5

	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	5's, /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	ISOCEF 400 mg capsule by M/s RECORDATI Chemical Industry and Pharmaceutical S.p.A. (Italy Approved)
	Me-too status	Xigris 400mg capsule by Wilshire/Horizon (Reg#053635)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
Dry Powder Suspension (Cephalosporin) Section 19 Products/10 Molecules		
1559.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Caflor 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefaclor (as monohydrate)…250mg
	Diary No, Date of R & I & fee	Dy.No 11193 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	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)
	GMP Status	Grant of DML
	Remarks of the Evaluator	19-02-2019 &22-02-2019 Grant of DML.Panel unanimously recommended grant of DML
	Decision: Approved.	
1560.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Caflor 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefaclor (as monohydrate)…250mg
	Diary No, Date of R & I & fee	Dy.No 11194 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	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)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1561.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Roxikef 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefadroxil (as monohydrate)…125mg
	Diary No, Date of R & I & fee	Dy.No 11195 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60ml /As per SRO
	Approval Status of product in Reference	ORACEFAL 125 mg / 5 ml powder for oral suspension by M/s

	Regulatory Authorities.	Bristol - Myers Squibb (ANSM Approved)
	Me-too status	Evacef Suspension 125mg/5ml by M/s Highnoon Laboratories, Lahore (Reg#011213)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1562.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Roxikef 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefadroxil (as monohydrate)…250mg
	Diary No, Date of R & I & fee	Dy.No 11196 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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.	Duricef 250mg/5ml by M/s Warner Chilcott , (USFDA Approved)
	Me-too status	Evacef Suspension 250mg/5ml by M/s Highnoon Laboratories, Lahore (Reg#011214)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1563.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Rinidef 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefdinir…125mg
	Diary No, Date of R & I & fee	Dy.No 11197 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1564.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Rinidef 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefdinir…250mg
	Diary No, Date of R & I & fee	Dy.No 11198 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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 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	As recorded for above application
	Remarks of the Evaluator	

	Decision: Approved.	
1565.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fixikef 100mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefixime (as trihydrate)…100mg
	Diary No, Date of R & I & fee	Dy.No 11199 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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.	Cefixime 100 mg/5 ml Powder for Oral Suspension by M/s Generics [UK] Ltd t/a Mylan (MHRA Approved)
	Me-too status	Stlicef dry suspension 100mg/5ml by M/s Treat Pharma (Reg#073247)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1566.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fixikef 200mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefixime (as trihydrate)…200mg
	Diary No, Date of R & I & fee	Dy.No 11200 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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.	Cefixime for oral suspension 200mg/5ml by M/s Aurobindo Pharma (USFDA approved)
	Me-too status	Biozil Dry Suspension 200mg/5ml by M/s Biolabs (Reg#054770)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1567.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Poxime 40mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefpodoxime (as proxetil)…40mg
	Diary No, Date of R & I & fee	Dy.No 11201 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1568.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Poxime 80mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefpodoxime (as proxetil)…80mg

	Diary No, Date of R & I & fee	Dy.No 11202 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	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.	Not confirmed
	Me-too status	Cefporite 80 mg/5ml DS Dry Suspension M/s Sharooq Pharmaceuticals (Reg#069443)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1569.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Zilacure 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefprozil (as monohydrate)…125mg
	Diary No, Date of R & I & fee	Dy.No 11203 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	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.	Cefprozil powder for suspension 125mg/5ml by M/s Aurobindo Pharma USA, Inc. (USFDA approved)
	Me-too status	Vegapro 125mg/5ml dry powder for Suspension by M/s Vega Pharmaceuticals (Reg. No. 078765)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1570.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Zilacure 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefprozil (as monohydrate)…250mg
	Diary No, Date of R & I & fee	Dy.No 11204 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	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.	Cefprozil powder for suspension 250mg/5ml by M/s Aurobindo Pharma USA, Inc. (USFDA approved)
	Me-too status	Vegapro 250mg/5ml dry powder for Suspension by M/s Vega Pharmaceuticals (Reg. No. 078764)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1571.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefuroxime (as axetil)…125mg
	Diary No, Date of R & I & fee	Dy.No 11206 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	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.	Zinnat Suspension 125mg/5ml by M/s Glaxo Wellcome UK Limited (MHRA Approved)
	Me-too status	Kefrox Suspension of M/s CCL Pharmaceuticals (Reg.# 026054)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1572.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cefuroxime (as axetil) …250 mg
	Diary No, Date of R & I & fee	Dy.No 11207 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	50ml (after reconstitution), As per SRO
	Approval Status of product in Reference Regulatory Authorities.	ZINNAT cefuroxime (as axetil) 250 mg/5mL granules for oral suspension by M/s Aspen Pharmacare Australia Pty Ltd (TGA Approved)
	Me-too status	Optik 250mg/5ml DS Dry Suspension M/s Wilshire Laboratories (Pvt) Ltd. (Reg#053644)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1573.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Curakef 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cephalexin (as monohydrate)…125mg
	Diary No, Date of R & I & fee	Dy.No 11208 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	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 (R#078699)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1574.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Curakef 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cephalexin (as monohydrate)…250mg
	Diary No, Date of R & I & fee	Dy.No 11209 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	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 250mg/5ml Powder for Oral Suspension by M/s Milpharm Limited (MHRA approved)
	Me-too status	Vegzin 250mg/5ml by M/s Vega Pharmaceuticals (R#078700)

	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1575.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Velofex 125mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cephradine…125mg
	Diary No, Date of R & I & fee	Dy.No 11210 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60ml, 90ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Licef Dry Powder Susp.125mg/5ml by M/s Wisdom (R#078532)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1576.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Velofex 250mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Cephradine…250mg
	Diary No, Date of R & I & fee	Dy.No 11211 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60ml, 90ml /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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1577.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Bitafen 90mg/5ml Dry Suspension
	Composition	Each 5 ml after reconstitution contains: Ceftibuten (as dihydrate)…90mg
	Diary No, Date of R & I & fee	Dy.No 11205 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	30ml, 60ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	CEDAX 90mg/5ml Dry Suspension by M/s Shionogi USA, Inc (USFDA approved)
	Me-too status	Xigris 90mg/5ml Dry Suspension by Wilshire/Horizon (R#053634)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
Dry Powder Vial (Sterile) (Cephalosporin) Section		

36 Products/10 Molecules		
1578.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fepime 500mg Injection
	Composition	Each Vial Contains: Cefepime (as hydrochloride)…500mg With L-Arginine
	Diary No, Date of R & I & fee	Dy.No 11139 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	4th Generation 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 500mg Injection by M/s Hospira, Inc. (USFDA approved)
	Me-too status	Uspime 500mg Injection by Usawa Pharma (R#060251)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1579.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fepime 1000mg Injection
	Composition	Each Vial Contains: Cefepime (as hydrochloride)…1 gm With L-Arginine
	Diary No, Date of R & I & fee	Dy.No 11140 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	4th Generation 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 1gm Injection by M/s Hospira, Inc. (USFDA approved)
	Me-too status	Uspime 500mg Injection by Usawa Pharma (R# 060250)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1580.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Fepime 2000mg Injection
	Composition	Each Vial Contains: Cefepime (as hydrochloride)…2gm With L-Ariginine
	Diary No, Date of R & I & fee	Dy.No 11141 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	4th Generation 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 2g Injection by M/s Hospira, Inc. (USFDA approved)
	Me-too status	Pimax Injection 2g by M/s Hilton Pharma (Reg#042114)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1581.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 250mg Injection IV
	Composition	Each vial contains:-

		Ceftriaxone (as sodium)…250mg
	Diary No, Date of R & I & fee	Dy.No 11145 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IV 250 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	Trixone 250mg IV Injection by M/s Aptcure (Pvt) Ltd (Reg#085225)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1582.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 500mg Injection IV
	Composition	Each vial contains:- Ceftriaxone (as sodium)…500mg
	Diary No, Date of R & I & fee	Dy.No 11146 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IV 500 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	Signum 500 mg Injection I.V by M/s Cherwel Pharmaceuticals (Pvt) Ltd (Reg#079307)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1583.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 1000mg Injection IV
	Composition	Each vial contains:- Ceftriaxone (as sodium)…1gm
	Diary No, Date of R & I & fee	Dy.No 11147 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IV 1 g powder and solvent for solution for injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	Signum 1 gm Injection I.V. by M/s Cherwel Pharmaceuticals (Pvt) Ltd (Reg#079308)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1584.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 2000mg Injection IV
	Composition	Each vial contains: Ceftriaxone (as sodium)…2 grams
	Diary No, Date of R & I & fee	Dy.No 11148 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IV Injection 2gm By M/s Roche Products Limited (MHRA approved)
	Me-too status	Titan 2gm IV Injection by M/S Macter Pharma (Reg No. 075825)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1585.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 250mg Injection IM
	Composition	Each vial contains:- Ceftriaxone (as sodium)…250mg
	Diary No, Date of R & I & fee	Dy.No 11142 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IM 250 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	Ceftiheim Injection IM 250mg by M/s Pakheim International Pharma (Pvt) Ltd (Reg#085193)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1586.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 500mg Injection IM
	Composition	Each vial contains:- Ceftriaxone (as sodium)…500mg
	Diary No, Date of R & I & fee	Dy.No 11143 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IM 500 mg Powder and Solvent for Solution for Injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	Rocimed 500mg Injection I.M by M/s Medicraft Pharmaceuticals (Pvt) Ltd (Reg#082030)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1587.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Niacef 1000mg Injection IM
	Composition	Each vial contains: Ceftriaxone (as sodium)…1gram
	Diary No, Date of R & I & fee	Dy.No 11144 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 IM 1 g powder and solvent for solution for injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	Lozone Injectin I.M 1gm by M/s Llyods Pharma (R#027052)
	GMP Status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Approved.	
1588.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef 250mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)…500mg
	Diary No, Date of R & I & fee	Dy.No 11150 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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.	Cefobid 250mg Powder and solvent for solution injection for intramuscular Use by M/s Pfizer Italia SRL (AIFA Italy Approved)
	Me-too status	CEFOBID Injection 0.25gm by M/s PFIZER (Reg#020651)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1589.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef 500mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)…500mg
	Diary No, Date of R & I & fee	Dy.No 11151 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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.	Cefobid 500mg Powder and solvent for solution injection for intramuscular Use by M/s Pfizer Italia SRL (AIFA Italy Approved)
	Me-too status	CEFOBID Injection 0.5gm by M/s PFIZER (Reg#013841)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1590.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef 1000mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)…1000mg
	Diary No, Date of R & I & fee	Dy.No 11152 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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.	CEFOBID 1g/3ml powder and solvent for solution for injection for intramuscular use by M/s Pfizer Italia SRL (AIFA Italy Approved)
	Me-too status	CEFOBID Injection 1gm by M/s PFIZER (Reg#008524)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1591.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef 2000mg Injection

	Composition	Each vial contains: Cefoperazone (as sodium)…2000mg
	Diary No, Date of R & I & fee	Dy.No 11153 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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.	CEFOBID 2 g powder for solution for injection for intravenous use by M/s Pfizer Italia SRL (AIFA Italy Approved)
	Me-too status	CEFOBID Injection 2gm by M/s PFIZER (Reg#013842)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1592.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Mitrox 250mg Injection
	Composition	Each vial contains: Ceftizoxime…….250mg
	Diary No, Date of R & I & fee	Dy.No 11154 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Third-generation cephalosporins
	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.	Not confirmed.
	Me-too status	Tezox 250mg Injection M/s Bosch Pharmaceuticals (Pvt.) Ltd (Reg#034859)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1593.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Mitrox 500mg Injection
	Composition	Each vial contains: Ceftizoxime…….500mg
	Diary No, Date of R & I & fee	Dy.No 11155 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	Third-generation cephalosporins
	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.	Not confirmed.
	Me-too status	Tezox 500mg Injection M/s Bosch Pharma (Reg#034852)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1594.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Mitrox 1000mg Injection
	Composition	Each vial contains: Ceftizoxime…….1000mg
	Diary No, Date of R & I & fee	Dy.No 11156 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019

	Pharmacological Group	Third-generation cephalosporins
	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.	Not confirmed.
	Me-too status	Tezox 1000mg Injection M/s Bosch Pharmaceuticals (Pvt.) Ltd (Reg#034853)
	GMP Status	As recorded for above application
	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 Registration Board in its 275th meeting.	
1595.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 250mg Injection
	Composition	Each vial contains: Cefuroxime (as sodium)…250mg
	Diary No, Date of R & I & fee	Dy.No 11157 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1596.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 500mg Injection
	Composition	Each vial contains: Cefuroxime (as sodium)…500mg
	Diary No, Date of R & I & fee	Dy.No 11158 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation 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.	Curoxim 500 mg powder and solvent for suspension for injection by M/s GlaxoSmithKline S.p.A. (AIFA Italy Approved)
	Me-too status	Optik 500mg Injection M/s 'Wilshire (Reg#071388)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1597.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 750mg Injection
	Composition	Each vial contains: Cefuroxime (as sodium)…750mg
	Diary No, Date of R & I & fee	Dy.No 11159 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1598.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Oxicure 1500mg Injection
	Composition	Each vial contains: Cefuroxime (as sodium)…1.5gm
	Diary No, Date of R & I & fee	Dy.No 11160 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	2nd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1599.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef Plus 250mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)....125mg Sulbactam (as sodium)....125mg
	Diary No, Date of R & I & fee	Dy.No 11161 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin + Beta Lactamase Inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	1's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Not confirmed.
	GMP Status	As recorded for above application
	Remarks of the Evaluator	• Approval Status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1600.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef Plus 500mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)....250mg Sulbactam (as sodium)....250mg
	Diary No, Date of R & I & fee	Dy.No 11162 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin + Beta Lactamase Inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP

	Pack Size & Demanded Price	1's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	2Sum Injection 500mg of M/s Sami Pharmaceuticals, Karachi (Reg.# 079941)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1601.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef Plus 1000mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)....500mg Sulbactam (as sodium)....500mg
	Diary No, Date of R & I & fee	Dy.No 11163 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin + Beta Lactamase Inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	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 1gm by M/s Bosch (Reg#037630)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1602.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Ricef Plus 2000mg Injection
	Composition	Each vial contains: Cefoperazone (as sodium)…1 gram Sulbactam (as sodium)…1 gram
	Diary No, Date of R & I & fee	Dy.No 11164 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation Cephalosporin + Beta Lactamase Inhibitor
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	1's /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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1603.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	P-Rome 500mg Injection
	Composition	Each vial contains: Cefpirome (as sulphate) 500mg
	Diary No, Date of R & I & fee	Dy.No 11165 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	4th generation cephalosporin
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	1's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefrom 0.5 g powder for solution for injection (IV) by M/s Sanofi Aventis France (ANSM Approved)
	Me-too status	Cefrom Injection 0.5gm by M/s Sanofi Aventis (Reg#021123)
	GMP Status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1604.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	P-Rome 1000mg Injection
	Composition	Each vial contains: Cefpirome (as sulphate) 1000mg
	Diary No, Date of R & I & fee	Dy.No 11166 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	4th generation cephalosporin
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	1's / As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cefrom 1 g powder for solution for injection (IV) by M/s Sanofi Aventis France (ANSM Approved)
	Me-too status	Cefrom Injection 1gm by M/s Sanofi Aventis (Reg#021124)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1605.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	C-Taz 250mg Injection
	Composition	Each vial contains: Ceftazidime (as pentahydrate)…250mg
	Diary No, Date of R & I & fee	Dy.No 11167 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 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	19-02-2019 &22-02-2019 Grant of DML Panel unanimously recommended grant of DML
	Remarks of the Evaluator	
	Decision: Approved.	
1606.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	C-Taz 500mg Injection
	Composition	Each vial contains: Ceftazidime (as pentahydrate)…500mg
	Diary No, Date of R & I & fee	Dy.No 11168 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1607.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	C-Taz 1000mg Injection
	Composition	Each vial contains:

		Ceftazidime (as pentahydrate)…1gm
	Diary No, Date of R & I & fee	Dy.No 11169 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1608.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Dimax 250mg Injection
	Composition	Each vial contains:- Cefotaxime (as sodium)....250mg
	Diary No, Date of R & I & fee	Dy.No 11170 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
1609.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Dimax 500mg Injection
	Composition	Each vial contains:- Cefotaxime (as sodium)....500mg
	Diary No, Date of R & I & fee	Dy.No 11171 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
1610.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Dimax 1000mg Injection
	Composition	Each vial contains:- Cefotaxime (as sodium)....1gm
	Diary No, Date of R & I & fee	Dy.No 11171 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	3rd Generation 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 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)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
1611.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Cefazol 250mg Injection
	Composition	Each vial contains: Cefazolin (as sodium)…250mg
	Diary No, Date of R & I & fee	Dy.No 11173 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation 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.	CEFAMEZIN 250 mg / 2 ml powder and solvent for solution for injection for intramuscular use by M/s PFIZER ITALIA S.r.l (AIFA Italy Approved)
	Me-too status	Cefamezin 250mg injection by M/s Barrett Hodgson (Reg#008126)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1612.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Cefazol 500mg Injection
	Composition	Each vial contains: Cefazolin (as sodium)…500mg
	Diary No, Date of R & I & fee	Dy.No 11174 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation 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.	Cefazolin For Injection 500mg by M/s Sandoz (USFDA Approved)
	Me-too status	Safelin Injection 500mg by M/s Fassgen Pharmaceuticals (Reg#074512)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1613.	Name and address of Manufacturer / Applicant	M/s Cure Laboratories (Pvt) Ltd., Plot No. 11&12, Street No. NS-2 National Industrial Zone, Rawat, Rawalpindi.
	Brand Name + Dosage Form + Strength	Cefazol 1000mg Injection
	Composition	Each vial contains: Cefazolin (as sodium)…1g
	Diary No, Date of R & I & fee	Dy.No 11175 dated 05-03-2019 Rs.20,000/- Dated 04-03-2019
	Pharmacological Group	1st Generation 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.	Cefazolin For Injection 1g by M/s Sandoz (USFDA Approved)
	Me-too status	Safelin Injection 1 gm by M/s Fassgen Pharma(Reg#074513)
	GMP Status	As recorded for above application

	Remarks of the Evaluator	
	Decision: Approved.	

M/s Greater Pharma Rawat Rawalpindi (New Licence)

CLB in its 269th meeting held on 26th Feb 2019 has considered and granted the Drug Manufacturing License (DML) to M/s Greater Pharma by **way of formulation** and granted (04) new section to the firm. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

Sr.No	Section	No. of Molecules	No of Products
1	Cream/Ointment section (General)	09	10
2	Topical Lotion Section (General)	08	08
3	Capsule Section (General)	10	13
4	Cream/Ointment Section (Steroid)	07	07
5	Topical Lotion Section (Steroid)	02	02

Cream/Ointment section (General)
10 Products/09 Molecules

1614.	Name and address of Manufacturer / Applicant	Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	Adben Gel
	Composition	Each gram contains Adapalene …1 mg (0.1%w/w) Benzoyl peroxide …25 mg (2.5%w/w)
	Diary No, Date of R & I & fee	Dy.No 13130 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	10 g, 15 g, 30 g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Epiduo 0.1% / 2.5% gel by M/s Galderma (UK) Ltd (MHRA Approved)
	Me-too status	Adalen e-B Gel by Pharmatec (Reg#076683)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have manufacturing facility to manufacture applied product.
	Decision: Deferred for evidence of required manufacturing facility for applied formulation since firm has approved section for Cream/Ointment (general) whereas applied formulation is a gel.	
1615.	Name and address of Manufacturer / Applicant	Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	Calciget Ointment 0.005 %w/w
	Composition	Each gram of Ointment tube contains Calcipotriol … 50 mcg (0.005%w/w)
	Diary No, Date of R & I & fee	Dy.No 13112 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Other antipsoriatics for topical use
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	30 g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Calcipotriol Ointment 50micrograms/g by M/s Sandoz Limited (MHRA Approved)
	Me-too status	Dervit Ointment 0.005%w/w by M/s Nabiqasim (R#067444)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1616.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Calcin-B Gel**
	Composition	Each gram of tube contains Clindamycin (as phosphate) …10 mg (1%w/w) Benzoyl peroxide …50 mg (5%w/w)
	Diary No, Date of R & I & fee	Dy.No 13119 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019

	Pharmacological Group	Anti-infectives for treatment of acne
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	10,15 & 25 g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Duac Once Daily 10mg/g + 50mg/g Gel by M/s GlaxoSmithKline UK Limited (MHRA Approved)
	Me-too status	Clingard- Gel by M/s Hoover Pharmaceuticals (Reg#064533)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have manufacturing facility to manufacture applied product.
	Decision: Deferred for evidence of required manufacturing facility for applied formulation since firm has approved section for Cream/Ointment (general) whereas applied formulation is a gel.	
1617.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Clacin Gel 1%w/w**
	Composition	Each gram contains Clindamycin (as phosphate) ……10 mg (1%w/w)
	Diary No, Date of R & I & fee	Dy.No 13118 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	RESIDERM 1%w/w GEL by M/s Crawford Healthcare Limited (MHRA Approved)
	Me-too status	Clindacin Gel 1%w/w by M/s Sante (Reg#067485)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have manufacturing facility to manufacture applied product.
	Decision: Deferred for evidence of required manufacturing facility for applied formulation since firm has approved section for Cream/Ointment (general) whereas applied formulation is a gel.	
1618.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Clacin-V Cream 2%w/w**
	Composition	Each gram contains Clindamycin (as phosphate) …20 mg (2%w/w)
	Diary No, Date of R & I & fee	Dy.No 13120 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	40g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Dalacin Cream 2%w/w By M/s Pfizer Ltd (MHRA Approved)
	Me-too status	Clinzen Cream 2%w/w by M/s Shrooq (Reg#040844)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1619.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Isogel-E Gel 0.5/20 mg**
	Composition	Each gram contains Isotretinoin …0.5mg (0.05%w/w) Erythromycin …20mg (2%w/w)
	Diary No, Date of R & I & fee	Dy.No 15496 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Retinoids and antiinfectives for topical use in acne
	Type of Form	Form-5
	Finished Product Specification	Innovator'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	Isogyl Gel of Noa Hemis (Reg#080623)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have manufacturing facility to manufacture applied product.
	Decision: Deferred for evidence of required manufacturing facility for applied formulation since firm has approved section for Cream/Ointment (general) whereas applied formulation is a gel.	
1620.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Renac Gel 2.5 %w/w**
	Composition	Each gram contains Ketoprofen ….....25mg (2.5 %w/w)
	Diary No, Date of R & I & fee	Dy.No 15497 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiinflammatory preparations, non-steroids for topical use
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	25g, 30g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Fastum 2.5% gel by M/s A Menarini Industrie Fa rmaceutiche Ruinite srl (MHRA Approved)
	Me-too status	Ticon 2.5 % w/w Gel of M/s Amarant, Karachi (Reg.# 070499)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have manufacturing facility to manufacture applied product.
	Decision: Deferred for evidence of required manufacturing facility for applied formulation since firm has approved section for Cream/Ointment (general) whereas applied formulation is a gel.	
1621.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Trago Cream 2%w/w**
	Composition	Each gram contains: Mupirocin (as calcium dihydrate) …20mg (2%w/w)
	Diary No, Date of R & I & fee	Dy.No 13107 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	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% cream by M/s GlaxoSmithKline (USFDA Approved)
	Me-too status	Mupiderm 2% Cream by M/s Tabros (Reg#070685)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1622.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Trico Ointment 0.1 %w/w**
	Composition	Each gram contains Tacrolimus (as monohydrate) …1mg
	Diary No, Date of R & I & fee	Dy.No 13106 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Agents for dermatitis, excluding corticosteroids
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	10g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Protopic 0.1% w/w ointment by M/s Astellas Ireland Co. Ltd (Netherlands Approved),

	Me-too status	Eczemus 0.1% Ointment by M/s Brookes Pharma (Reg#045493)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1623.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Terbiget Cream 1%w/w**
	Composition	Each gram contains Terbinafine hydrochloride ...10 mg (1%w/w)
	Diary No, Date of R & I & fee	Dy.No 13108 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	10g, 15g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Terbinafine Hydrochloride 1 % Cream By M/s Generics [UK] Limited t/a Mylan (MHRA Approved)
	Me-too status	Bina 1.0% Cream by M/s Linta pharmaceuticals (Pvt) Limited , Islamabad (Reg.# 080268)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
	Topical Lotion Section (General) 08 Products/08 Molecules	
1624.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Hairget Solution 5 %w/v**
	Composition	Each ml contains Minoxidil ….50 mg (5% w/v)
	Diary No, Date of R & I & fee	Dy.No 15498 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Other dermatologicals
	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.	Regaine for Men Extra Strength Scalp Solution 5% w/v Cutaneous Solution by M/s McNeil Products Limited (MHRA Approved)
	Me-too status	Higrow Topical Solution 5%w/v by M/s Shaigan (R#052658)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
1625.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Ciclo-G Lotion 1.5%w/w**
	Composition	Each gram contains: Ciclopirox olamine…15mg (1.5% w/w)
	Diary No, Date of R & I & fee	Dy.No 16720 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Other antifungals for topical use
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60ml ,90ml, 120ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Stieprox 15mg/g Shampoo by M/s GlaxoSmithKline (Ireland) Limited (HPRA Ireland Approved)
	Me-too status	Stieprox Topical Liquid by M/s GSK (Reg#026392)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	

	Decision: Approved.	
1626.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**D.Clor Lotion 20%w/v**
	Composition	Each ml of Lotion contains Aluminium chloride hexahydrate……..200 mg (20% w/v)
	Diary No, Date of R & I & fee	Dy.No 16711 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Other anti-acne preparations for topical use
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	60ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Anhydrol Forte 20% w/v Cutaneous Solution by M/s Diomed Developments Limited (MHRA Approved)
	Me-too status	Not confirmed.
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm has applied as lotion whereas formulation approved by MHRA is solution. • 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.	
1627.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**G-Mith Lotion**
	Composition	Each100 ml lotion Contains: Permethrin …0.5gm Crotamiton …10 g
	Diary No, Date of R & I & fee	Dy.No 16708 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Scabicidal preparation
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	100ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Not confirmed.
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• The formulation applied by the firm is not approved by DRAP nor in Reference Regulatory Authorities. • Firm has submitted that it wants to revise formulation to: Each gram Contains: Permethrin …50mg (5%w/w) • Approval Status of revised product in Reference Regulatory Authorities is KWELLADA-P LOTION 5% w/w by M/s MEDTECH PRODUCTS INC (Health Canada Approved) • Me-too status of revised product is Bioscab lotion 5% by M/s Bio-Labs (Reg#054774)
	Decision: Deferred for further deliberation.	
1628.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Ketocare Lotion 2 %w/w**
	Composition	Each gram contain: Ketoconazole…20mg (2%w/w)
	Diary No, Date of R & I & fee	Dy.No 16718 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Imidazole and triazole derivatives
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications

	Pack Size & Demanded Price	60ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Nizoral Anti-Dandruff Shampoo 2%w/w by M/s McNeil Products Limited (MHRA Approved)
	Me-too status	Ketonaz Lotion by M/s Sante (Reg#073453)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm initially applied as w/v whereas formulation approved by MHRA is w/w. • Firm has revised formulation on w/w basis with submission of fee of Rs. 5000/- (Challan#0844646) Dated 09-05-2019
	Decision: Approved with innovator's specification.	
1629.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Clacin-L Lotion 1%w/v**
	Composition	Each ml contains: Clindamycin (as phosphate) …10mg (1%w/v)
	Diary No, Date of R & I & fee	Dy.No 16714 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antiinfectives for treatment of acne
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	30ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Dalacin T Topical Lotion by M/s Star Pharmaceuticals Ltd (MHRA Approved)
	Me-too status	Austaclin-T Lotion by M/s Bloom Pharmaceuticals (Pvt) Ltd (Reg#063077)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1630.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Silkin 10%w/w Lotion**
	Composition	Each mg contains Urea ……100 mg (10 % w/w)
	Diary No, Date of R & I & fee	Dy.No 16716 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Carbamide products(hydrating and keratolytic agent)
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	50ml, 60ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	EUCERIN INTENSIVE 10% W/W UREA TREATMENT LOTION. By M/s Beiersdorf UK Limited, (HPRA, Ireland Approved)
	Me-too status	Not confirmed.
	GMP Status	20-12-2017 Panel recommends grant of DML.
	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.	
1631.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Flucel Lotion 5 %w/w**
	Composition	Each gram contains Fluorouracil ……50mg (5%w/w)
	Diary No, Date of R & I & fee	Dy.No 16717 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antimetabolites (Pyrimidine analogues)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	25ml, 10ml /As per SRO

	Approval Status of product in Reference Regulatory Authorities.	Efudex topical solution 5%w/w by M/s ICN Pharmaceuticals (USFDA Approved)
	Me-too status	Not confirmed.
	GMP Status	20-12-2017 Panel recommends grant of DML.
	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.	
Capsule Section (General)) 13 Products/10 Molecules		
1632.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Tricin Capsule 250 mg**
	Composition	Each capsule contains: Azithromycin (as dihydrate) …250mg
	Diary No, Date of R & I & fee	Dy.No 13111 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x6's 5x6's & 1x10's As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Azithromycin 250 mg Capsules by Jubilant Pharmaceuticals nv. (MHRA approved)
	Me-too status	Azofas 250mg Capsules by Fassgen Pharmaceuticals. (Reg#060291)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1633.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Esocap Capsule 40 mg**
	Composition	Each capsule contains: Esomeprazole magnesium trihydrate (as enteric coated pellets 22.5%) eq. to Esomeprazole……40mg
	Diary No, Date of R & I & fee	Dy.No 13110 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	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.	NEXIUM® (esomeprazole magnesium) 40mg delayed release capsules, for oral use by Astra Zeneca Pharms. (USFDA approved)
	Me-too status	Obpra Capsule 40mg by Obson Pharma. (Reg#054166)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Source of pellets:Vision Pharmaceuticals, Islamabad
	Decision: Approved.	
1634.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Well-P capsule 0.4 mg**
	Composition	Each capsule contains: Tamsulosin hydrochloride (as SR pellets 0.2%) …0.4mg
	Diary No, Date of R & I & fee	Dy.No 13109 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Alpha adrenergic antagonist
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 20's , 30's . As per SRP
	Approval Status of product in Reference Regulatory Authorities.	Flomax 0.4mg capsule by M/s Boehringer Ingelheim Pharmaceuticals (USFDA Approved)

	Me-too status	Tamflo 0.4mg SR Capsule by M/s Genome Pharma (Reg#074562)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Source of pellets:Vision Pharmaceuticals, Islamabad
	Decision: Approved.	
1635.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Lozna Capsule 100 mg**
	Composition	Each Capsule contains Danazol..... …100 mg
	Diary No, Date of R & I & fee	Dy.No 13116 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antigonadotropins and similar agents
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30's, 100's/ As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Danazol Capsules 100mg by M/s Generics (UK) Ltd t/a Mylan (MHRA Approved)
	Me-too status	Serocrime100mg Capsules by Hilton (Reg#013162)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have capsule steroid section to manufacture applied product.
	Decision: Deferred for confirmation of requisite section for the applied product.	
1636.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Lozna Capsule 200 mg**
	Composition	Each Capsule contains Danazol..... …200 mg
	Diary No, Date of R & I & fee	Dy.No 13117 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antigonadotropins and similar agents
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30's, 100's/ As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Danazol Capsules 200mg by M/s Generics (UK) Ltd t/a Mylan (MHRA Approved)
	Me-too status	Danzol 200mg Capsules by Platinum Pharma (Reg#034832)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm does not have capsule steroid section to manufacture applied product.
	Decision: Deferred for confirmation of requisite section for the applied product.	
1637.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Olanzatin 3mg/25mg Capsule**
	Composition	Each capsule contains: Olanzapine…3mg Fluoxetine (as hydrochloride) …25mg.
	Diary No, Date of R & I & fee	Dy.No 15492 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antidepressants in combination with psycholeptics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	14's & 30's / As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Symbyax 3mg/25mg capsule by Eli Lilly (USFDA Approved)
	Me-too status	Co-Depricap 3/25mg Capsule by M/s Nabi Qasim Industries Pvt.Ltd. (Reg#076136)
	GMP Status	20-12-2017 Panel recommends grant of DML.

	Remarks of the Evaluator	
	Decision: Approved.	
1638.	Name and address of Manufacturer / Applicant	Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	Olanzatin 6mg/25mg Capsule
	Composition	Each capsule contains: Olanzapine…6mg Fluoxetine (as hydrochloride) …25mg.
	Diary No, Date of R & I & fee	Dy.No 15493 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antidepressants in combination with psycholeptics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	14's & 30'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	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1639.	Name and address of Manufacturer / Applicant	Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	Olanzatin 12mg/25mg Capsule
	Composition	Each capsule contains: Olanzapine…12mg Fluoxetine (as hydrochloride) …25mg.
	Diary No, Date of R & I & fee	Dy.No 15494 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	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 12mg/25mg capsule by Eli Lilly (USFDA Approved)
	Me-too status	Olanco Capsules 12/25mg by M/s Genome (Reg#064014)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1640.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Premac Capsule 100 mg**
	Composition	Each Capsule contains: Pregabalin …100mg
	Diary No, Date of R & I & fee	Dy.No 13115 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antiepileptics
	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.	Alzain 100 mg Capsules, Hard by Dr. Reddy's Laboratories (UK) Ltd, (MHRA approved)
	Me-too status	Zeegap 100mg Capsules by Hilton Pharma (REG#047360)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1641.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Fungi-D capsule 150 mg**

	Composition	Each capsule contains: Fluconazole …150mg
	Diary No, Date of R & I & fee	Dy.No 13114 dated 06-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antimycotics For Systemic Use
	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.	Fluconazole 150mg capsule by Bristol Laboratories Limited. (MHRA approved)
	Me-too status	Fungon Capsules 150mg by Dyson Research Laboratories. (Reg#055353)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1642.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Gybix Capsule 60 mg**
	Composition	Each Capsule contains Duloxetine Hydrochloride (as 17% enteric coated pellets) eq. to Duloxetine …60mg
	Diary No, Date of R & I & fee	Dy.No 15495 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	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.	Cymbalta (Duloxetine 60 mg capsule) by M/s Eli Lilly, (USFDA Approved)
	Me-too status	Dulan (Duloxetine 60 mg capsule) by M/s Hilton (R#055448)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Source of pellets: M/s Vision Pharmaceuticals, Islamabad
	Decision: Approved.	
1643.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Refit Capsule 120 mg**
	Composition	Each capsule contains: Orlistat …120mg
	Diary No, Date of R & I & fee	Dy.No 16710 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Peripherally acting antiobesity products
	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.	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	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Source of pellets not submitted by the firm.
	Decision: Deferred for submission of source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1644.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Brotin Capsule 5 mg**
	Composition	Each Capsule contains Bromocriptine (as mesylate) …5 mg
	Diary No, Date of R & I & fee	Dy.No 16719 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Prolactine inhibitors
	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.	Parlodel 5mg Capsules by M/s Mylan Products Ltd (MHRA Approved)
	Me-too status	Parlodel Capsule 5mg by M/s Sandoz (Reg#013745)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation of manufacturing facility.	
Cream/Ointment Section (Steroid) 07 Products/07 Molecules		
1645.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Closol Cream 0.05%w/w**
	Composition	Each gram Contains: Clobetasol Propionate… 0.5mg (0.05%w/w)
	Diary No, Date of R & I & fee	Dy.No 16707 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, very potent (group IV)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	30 g. /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	ClobaDerm 500 micrograms/g Cream by Auden Mckenzie Pharma Division Ltd. (MHRA approved)
	Me-too status	Clobicare Cream by Martin Dow Ltd. (Reg#067938)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1646.	Name and address of Manufacturer / Applicant	Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	Beta-N Cream
	Composition	Each gram contains: Betamethasone (as valerate)…1mg Neomycin sulphate…….5mg
	Diary No, Date of R & I & fee	Dy.No 16721 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification
	Pack Size & Demanded Price	15g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Betnovate® N Cream by Suerte Pharma Ltd. (MHRA Approved)
	Me-too status	Betnovate-N Cream by GSK (Reg#000254)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm initially applied as Betamethasone …1mg, whereas formulation approved by MHRA is Betamethasone (as valerate) …1mg. • Firm has revised formulation with submission of fee of Rs. 5000/- (Challan#0844645) Dated 09-05-2019
	Decision: Approved with innovator's specification.	
1647.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Beta-D Cream 0.05 %w/w**
	Composition	Each gram Contains: Betamethasone (as dipropionate) … 0.5mg (0.05%w/w)
	Diary No, Date of R & I & fee	Form-5 Dy.No 16722 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Diprosone Cream 0.05%w/w by M/s MERCK CANADA INC (Health Canada Approved)
	Me-too status	Novasone Cream 0.05% by M/s Mass Pharma (Reg#024371)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1648.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Clear –M Cream**
	Composition	Each gram contains: Hydroquinone …40mg(4 %w/w) Fluocinolone acetonoide …0.1mg (0.01 %w/w) Tretinoin …0.5mg(0.05%w/w)
	Diary No, Date of R & I & fee	Dy.No 16713 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification
	Pack Size & Demanded Price	15g, 30g/As per SRO
	Approval Status of product in Reference Regulatory Authorities.	TRI-LUMA® (fluocinolone acetonide,hydroquinone, and tretinoin) cream, 0.01%, 4%, 0.05% for topical use by Galderma Labs LP. (USFDA approved)
	Me-too status	Trimelasin Cream by Valor Pharmaceuticals. (Reg#031104)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1649.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Beta-F Cream**
	Composition	Each gram contains Fusidic acid …20 mg (2%w/w) Betamethasone (as valerate) …1 mg (0.1%w/w)
	Diary No, Date of R & I & fee	Dy.No 16723 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, combinations with antibiotics
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification
	Pack Size & Demanded Price	15g /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream by Goapharma. (MHRA approved)
	Me-too status	Fusivate Cream by Macter International. (Reg#033014)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1650.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**FUGET– H Cream**
	Composition	Each gram contains: Fusidic acid….20 mg (2% w/w) Hydrocortisone acetate…..10 mg (1% w/w)
	Diary No, Date of R & I & fee	Dy.No 16712 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, combinations with antibiotics
	Type of Form	Form-5
	Finished Product Specification	Innovator's Specification
	Pack Size & Demanded Price	15g /As per SRO

	Approval Status of product in Reference Regulatory Authorities.	Fucidin H Cream by LEO Laboratories Limited. (MHRA approved)
	Me-too status	Mirazym Cream of M/s Hiranis Karachi (Reg.# 076516)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
Topical Lotion Section (Steroid) 02 Products/02 Molecules		
1651.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Cloget Topical Solution 0.05%w/v**
	Composition	Each ml Contains: Clobetasol Propionate…0.5mg (0.05%w/v)
	Diary No, Date of R & I & fee	Dy.No 16709 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, very potent (group IV)
	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.	clobetasol propionate topical solution, 0.05%w/v by M/s Actavis (USFDA Approved)
	Me-too status	Clobicare Lotion by Seatle (Reg#083857)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	
	Decision: Approved.	
1652.	Name and address of Manufacturer / Applicant	**Greater Pharma.** Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name + Dosage Form + Strength	**Besa Lotion**
	Composition	Each gram contains: Betamethasone (as dipropionate) …0.5mg (0.05%w/w) Salicylic acid …20mg (2% w/w)
	Diary No, Date of R & I & fee	Dy.No 16715 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Corticosteroids, potent, combinations with kertolytic agent
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	50ml /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Diprosalic Scalp Application 0.05% w/w / 2% w/w, cutaneous solution by M/s Merck Sharp & Dohme Limited (MHRA Approved)
	Me-too status	Betamet-S Lotion by M/s Seatle (Private) Limited (Reg#083858)
	GMP Status	20-12-2017 Panel recommends grant of DML.
	Remarks of the Evaluator	• Firm initially applied as: Each ml contains: Betamethasone …0.5mg (0.05%w/v) Salicylic acid …30mg (3% w/v) Now firm has revised the formulation to: Each gram contains: Betamethasone (as dipropionate) …0.5mg (0.05%w/w) Salicylic acid …20mg (2% w/w) • Firm has revised formulation with submission of fee of Rs. 20,000/- (Challan#0844647) Dated 09-05-2019
	Decision: Approved with innovator's specification.	

b. NEW/ADDITIONAL SECTION(S)

M/ s Berlex Lab International.., Multan (New section)

CLB in its 226th meeting held on 31st December 2010 has considered and granted new section to M/ s Berlex Lab International.., Multan.

Firm submitted on 02-04-2019 that no product has yet been registered for psychotropic tablet section and they may be allowed 10 products as per policy.

Firm's application was sent to Reg-II section on 08-05-2019 to confirm if any products of Tablet (Psychotropic) Section have been registered till date for further processing.

Reg-II section replied on 09-05-2019 that as per record available in section, none of Tablet (Psychotropic) is found registered on the name of applicant.

Sr.No	Section	No. of Products
1	Tablet (Psychotropic) Section	10

Tablet (Psychotropic) Section 10 Products		
1653.	Name and address of Manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	Xulax 2mg Tablet
	Composition	Each Tablet Contains: Alprazolam…2mg
	Diary No, Date of R & I & fee	Dy.No 42717 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Benzodiazepine Derivative
	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.	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 (Pvt.) Ltd. (Reg#079370)
	GMP Status	30-01-2018 & 09-04-2018. Renewal of DML and grant of additional sections. Panel recommends Renewal of DML and grant of additional sections.
	Remarks of the Evaluator	
	Decision: Approved.	
1654.	Name and address of Manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	Xulax 1mg Tablet
	Composition	Each Tablet Contains: Alprazolam…1mg
	Diary No, Date of R & I & fee	Form-5 Dy.No 42706 (13-12-2018) Rs.20,000/- 13-12-2018
	Pharmacological Group	Benzodiazepine Derivative
	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.	ALPRAZOLAM MYLAN 1 mg, scored tablet by M/s MYLAN SAS (ANSM France Approved)
	Me-too status	Alprazolam 1 mg Tablets by M/s Heal Pharma (Reg#079392)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1655.	Name and address of Manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	Xulax 0.5mg Tablet
	Composition	Each Tablet Contains: Alprazolam…0.25mg
	Diary No, Date of R & I & fee	Dy.No 42705 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018

	Pharmacological Group	Benzodiazepine Derivative
	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.	Xanax 500 microgram Tablets by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Azolam Tablet 0.5mg by M/s Tas Pharmaceuticals (Reg#016521)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1656.	Name and address of Manufacturer / Applicant	**M/s Berlex Lab International.** 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	**Xitonil 3mg Tablet**
	Composition	Each Tablet Contains: Bromazepam…3mg
	Diary No, Date of R & I & fee	Dy.No 42707 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Benzodiazepine derivatives
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	3x10's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Lexotan 3mg Tablets by M/s Roche Products Limited (HPRA Ireland Approved)
	Me-too status	Bromota Tablet 3mg by M/s Orta Laboratories (Reg#065938)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1657.	Name and address of Manufacturer / Applicant	**M/s Berlex Lab International.** 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	**Xovibar 30mg Tablet**
	Composition	Each Tablet Contains: Phenobarbitone…30mg
	Diary No, Date of R & I & fee	Dy.No 42702 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Barbiturates and derivatives
	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.	Phenobarbitone 30 mg Tablets by M/s Bristol Laboratories Limited (MHRA Approved)
	Me-too status	ALEPTAL Tablet 30mg by M/s Bloom Pharmaceuticals (Pvt) Ltd (Reg#080596)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1658.	Name and address of Manufacturer / Applicant	**M/s Berlex Lab International.** 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	**Xepam 10mg Tablet**
	Composition	Each Tablet Contains: Diazepam…10mg
	Diary No, Date of R & I & fee	Dy.No 42713 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Benzodiazepine derivatives
	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.	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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1659.	Name and address of Manufacturer / Applicant	**M/s Berlex Lab International.** 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	**Xepam 5mg Tablet**
	Composition	Each Tablet Contains: Diazepam…5mg
	Diary No, Date of R & I & fee	Dy.No 42712 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Benzodiazepine derivatives
	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.	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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1660.	Name and address of Manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	Ritaxin 10mg Tablet
	Composition	Each Tablet Contains: Methylphenidate Hydrochloride…10mg
	Diary No, Date of R & I & fee	Dy.No 42703 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Centrally acting sympathomimetics
	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.	METHYLPHENIDATE HYDROCHLORIDE Tablet by M/s SPECGX LLC (USFDA Approved)
	Me-too status	Phenida Tablets 10mg by M/s Zafa (Reg#034745)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1661.	Name and address of Manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	Bupnar 0.2mg Tablet
	Composition	Each Tablet Contains: Buprenorphine as hydrochloride…0.2mg
	Diary No, Date of R & I & fee	Dy.No 42709 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Analgesics (Oripavine derivatives)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack Size & Demanded Price	5x10's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Bunex 0.2mg Tablet by M/s Safe Pharma (Reg#053395)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	Firm has applied as uncoated tablet whereas formulation approved in MHRA and TGA is sublingual tablet.
	Decision: Deferred for revision of formulation and requsite fee.	

1662.	Name and address of Manufacturer / Applicant	M/s Berlex Lab International. 10-Km, Nagshah Chowk, Karachi Road, Multan.
	Brand Name + Dosage Form + Strength	Zolpida 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Zolpidem Tartrate…10mg
	Diary No, Date of R & I & fee	Dy.No 42684 dated 13-12-2018 Rs.20,000/- Dated 13-12-2018
	Pharmacological Group	Benzodiazepine related drugs
	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.	Zolpidem 10 mg Film-Coated Tablets by M/s Generics [UK] Limited (MHRA Approved)
	Me-too status	Somnia 10mg Tablets by M/s Wilshire Laboratories (R#067737)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	

Case No. 03 Registration Applications of Categories to be Considered on Priority.

a. Export Facilitation.

Applications was received through letter No.F.7-7/2017-Reg-II (Vol-III) dated: 30-04-2019
"**M/s Tabros Pharma Pvt Ltd.**Karachi have achieved benchmark of USD 762,638.93/- during fiscal year 2017-2018. In this regard, please find the (5 molecule) applications:

1663.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Trozar 40mg Tablet
	Composition	Each film coated tablet contains; Atorvastatin (as calcium trihydrate) …40mg
	Diary No, Date of R & I & fee	Dy.No 37270 dated 12-11-2018 Rs.20,000/- Dated 12-11-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	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.	Atorvastatin 40 mg film-coated tablets by M/s KRKA, d.d., (MHRA Approved)
	Me-too status	Lipitor Tablets 40mg by M/s Parke-Davis (Reg#023622)
	GMP Status	25-10-2018 Routine GMP inspection cGMP compliance level is rated as good.
	Remarks of the Evaluator	
	Decision: Approved.	
1664.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Trozar 20mg Tablets
	Composition	Each film coated tablet contains; Atorvastatin (as calcium trihydrate) …20mg
	Diary No, Date of R & I & fee	Dy.No 37271 dated 12-11-2018 Rs.20,000/- Dated 12-11-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	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.	Atorvastatin 20 mg film-coated tablets by M/s KRKA, d.d., (MHRA Approved)
	Me-too status	Lipitor Tablets 20mg by M/s Parke-Davis (Reg#023621)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	

1665.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Trozar 10mg Tablets
	Composition	Each film coated tablet contains; Atorvastatin (as calcium trihydrate) …10mg
	Diary No, Date of R & I & fee	Dy.No 37272 dated 12-11-2018 Rs.20,000/- Dated 12-11-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	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.	Atorvastatin 10 mg film-coated tablets by M/s KRKA, d.d., (MHRA Approved)
	Me-too status	Lipitor Tablets 10mg by M/s Parke-Davis (Reg#023620)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1666.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Zynamite 6.4mg Tablet**
	Composition	Each Sustained Release Tablet Contains: Glyceryl Trinitrate…6.4mg
	Diary No, Date of R & I & fee	Dy.No 44234 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Vasodilators used in cardiac diseases (Organic nitrates)
	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.	SUSTAC Prolonged release tablets 6.4MG by M/s CHEMIDEX PHARMA LIMITED (MHRA Approved)
	Me-too status	Slotac SR tablet 6.4mg of M/s Werrick (Reg#025168)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1667.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Zynamite 2.6mg Tablet**
	Composition	Each Sustained Release Tablet Contains: Glyceryl Trinitrate…2.6mg
	Diary No, Date of R & I & fee	Dy.No 44235 dated 28-12-2018 Rs.20,000/- Dated 28-12-2018
	Pharmacological Group	Vasodilators used in cardiac diseases (Organic nitrates)
	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.	SUSTAC Prolonged release tablets 2.6MG by M/s CHEMIDEX PHARMA LIMITED (MHRA Approved)
	Me-too status	Slotac SR tablet 2.6mg of M/s Werrick (Reg#025167)
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1668.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Ansifix 50mg Tablet**
	Composition	Each film-coated tablet Contains: Sitagliptin (as phosphate monohydrate) …50mg
	Diary No, Date of R & I & fee	Dy.No 2904 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	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	As recorded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1669.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Ansifix 25mg Tablet**
	Composition	Each film-coated tablet Contains: Sitagliptin (as phosphate monohydrate) …25mg
	Diary No, Date of R & I & fee	Dy.No 2903 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	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 25 mg film-coated tablet by M/s Merck Sharp Dohme (USFDA Approved)
	Me-too status	A-Glip 25mg Tablets by M/s Atco (Reg#053096)
	GMP Status	As recoded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1670.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Ansifix 100mg Tablet**
	Composition	Each film-coated tablet Contains: Sitagliptin (as phosphate monohydrate) …100mg
	Diary No, Date of R & I & fee	Dy.No 2905 dated 22-01-2019 Rs.20,000/- Dated 22-01-2019
	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 100 mg 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	As recoded for above application
	Remarks of the Evaluator	
	Decision: Approved.	
1671.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Ansiget 50/500mg Tablet**
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as phospate monohydrate) …50mg Metformin hydrochloride…500mg
	Diary No, Date of R & I & fee	Form-5 Dy.No 6201 dated 13-02-2019 Rs.20,000/- 12-02-2019
	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.	Janumet 50/500 mg film coated Tablet by Merck Sharp & Dohme (Australia) Pty Ltd (TGA Approved)
	Me-too status	Treviamet 50mg/500mg Tablets by M/s GETZ Pharma Pakistan (Reg# 055443)
	GMP Status	As recoded for above application

	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1672.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ansiget 50/850mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as phospate monohydrate) …50mg Metformin hydrochloride…850mg
	Diary No, Date of R & I & fee	Dy.No 6200 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	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.	Janumet 50/850 mg film coated Tablet by Merck Sharp & Dohme (Australia) Pty Ltd (TGA Approved)
	Me-too status	Treviamet 50mg + 850mg Tablet by Getz (Reg# 083315)
	GMP Status	As recoded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1673.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Ansiget 50/1000mg Tablet
	Composition	Each Film Coated Tablet Contains: Sitagliptin (as phospate monohydrate) …50mg Metformin hydrochloride…1000mg
	Diary No, Date of R & I & fee	Dy.No 6199 dated 13-02-2019 Rs.20,000/- Dated 12-02-2019
	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.	Janumet 50/1000 mg film coated Tablet by Merck (USFDA Approved)
	Me-too status	Treviamet 50mg + 1000mg Tablet by Getz (Reg# 055444)
	GMP Status	As recoded for above application
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
1674.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Colostan 3MIU IV powder for Injection and Infusion
	Composition	Each vial contains: Colistimethate Sodium 3million international units IU eq to.....….240mg
	Diary No, Date of R & I & fee	Dy.No 8145 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Other antibacterials (Polymyxins)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Colistimethate sodium 3 MIU, powder for solution for injection by M/s PANMEDICA (MHRA Approved)
	Me-too status	Not confirmed.
	GMP Status	As recoded for above application
	Remarks of the Evaluator	• Me-too status not confirmed from available database.
	Decision: Deferred for submission of application on requisite form and differential fee and stability study data as per the requirements of 278th meeting of Registration Board.	

1675.	Name and address of Manufacturer / Applicant	M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	Colostan 2MIU IV powder for Injection and Infusion
	Composition	Each vial contains: Colistimethate Sodium 2million international units IU eq to…160mg
	Diary No, Date of R & I & fee	Dy.No 8144 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Other antibacterials (Polymyxins)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Colistimethate sodium 2 MIU, powder for solution for injection by M/s PANMEDICA (MHRA Approved)
	Me-too status	Not confirmed.
	GMP Status	As recoded for above application
	Remarks of the Evaluator	• Me-too status not confirmed from available database.
	Decision: Deferred for submission of application on requisite form and differential fee and stability study data as per the requirements of 278th meeting of Registration Board.	
1676.	Name and address of Manufacturer / Applicant	**M/s Tabros Pharma Pvt Ltd.** L-20/B,Sector-22, Federal B Industrial Area, Karachi.
	Brand Name + Dosage Form + Strength	**Colostan 1MIU IV powder for Injection and Infusion**
	Composition	Each vial contains: Colistimethate Sodium 1million international units IU eq to…80mg
	Diary No, Date of R & I & fee	Dy.No 8143 dated 25-02-2019 Rs.20,000/- Dated 25-02-2019
	Pharmacological Group	Other antibacterials (Polymyxins)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 10's /As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Colistimethate sodium 1 MIU, powder for solution for injection by M/s PANMEDICA (MHRA Approved)
	Me-too status	Colistat powder for Injection 1MIU by M/s Medisure (Reg#076160)
	GMP Status	As recoded for above application
	Remarks of the Evaluator	
	Decision: Approved.	

Case No. 04 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1677.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd; Plot No. E-127, E-128 & E-129 North Western Industrial Zone, Bin Qasim, Karachi.	Cinacal Tablets 30mg Each film coated tablet contains: Cinacalcet (as hydrochloride)… 30mg Anti-Parathyroid Agents (Other anti-parathyroid agents)	Form 5 Dairy No. 17988 dated 12-10-2017. Rs.20,000/- dated 28-09-2017. As per SRO, for 10's. As per SRO, for 20's. As per SRO, for 30's.	SENSIPAR (cinacalcet) film-coated tablet 30mg by M/s Amgen Inc. (USFDA approved) Mimcipar 30mg Tablet by M/s Genome (Reg#082301) Copy of GMP inspection report dated 18 & 31-07-

		Manufacturer's Specifications.		2017 recommending renewal of DML.

STABILITY STUDY DATA			
Drug	Cinacal Tablets 30mg (Cinacalcet)		
Name of Manufacturer	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd; Plot No. E-127, E-128 & E-129 North Western Industrial Zone, Bin Qasim, Karachi.		
Manufacturer of API	Enaltec Labs Pvt. Ltd, 1706, 17th Floor, Plot No. 5, Kesar Solitaire, Sector-19, Navi Mumbai. Sanpada-40070, Dist-Thane-Zone7, India.		
API Lot No.	EL-03/A100/16002		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	September 2017	Feburary 2018	Feburary 2018
Date of Initiation	December 2017	March 2018	March 2018
No. of Batches	03		
Date of Submission	19-11-2018 (Dy. No. 38035)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents to Be Provided**	**Status**
1)	COA of API	Copy of COA for Cinacalcet hydrochloride from M/s Enaltec Labs Pvt. 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.	Photocopy of GMP Certificate No. 6078745 for Alembic Pharmaceuticals Limited, India issued by Food and Drugs Administration, Maharashtra, India is submitted. Valid till 05-12-2018.
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 Invoice submitted by the firm confirms import of 360.1grams Cinacalcet hydrochloride via DHL. Batch no. is mentioned in invoice. Invoice is not ADC 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,	Yes

	1978.			
Evaluation by PEC: • Invoice is not attested by ADC.				
Decision:				
Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability** **GMP Inspection Report Date & Remarks**
1678.	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd; Plot No. E-127, E-128 & E-129 North Western Industrial Zone, Bin Qasim, Karachi.	Cinacal Tablets 60mg Each film coated tablet contains: Cinacalcet (as hydrochloride)… 60mg Anti-Parathyroid Agents (Other anti-parathyroid agents) Manufacturer's Specifications.	Form 5 Dairy No. 17989 dated 12-10-2017. Rs.20,000/- dated 28-09-2017. As per SRO, for 10's. As per SRO, for 20's. As per SRO, for 30's.	SENSIPAR (cinacalcet) film-coated tablet 60mg by M/s Amgen Inc. (USFDA approved) Mimcipar 60mg Tablet by M/s Genome (Reg#082302) Copy of GMP inspection report dated 18 & 31-07-2017 recommending renewal of DML.

STABILITY STUDY DATA

Drug	Cinacal Tablets 60mg (Cinacalcet)		
Name of Manufacturer	M/s. Kaizen Pharmaceuticals (Pvt.) Ltd; Plot No. E-127, E-128 & E-129 North Western Industrial Zone, Bin Qasim, Karachi.		
Manufacturer of API	Enaltec Labs Pvt. Ltd, 1706, 17th Floor, Plot No. 5, Kesar Solitaire, Sector-19, Navi Mumbai. Sanpada-40070, Dist-Thane-Zone7, India.		
API Lot No.	EL-03/A100/16002		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	TF-01	TF-02	TF-03
Batch Size	1500 Tablets	1000 Tablets	1000 Tablets
Manufacturing Date	October 2017	Feburary 2018	Feburary 2018
Date of Initiation	December 2017	March 2018	March 2018
No. of Batches	03		
Date of Submission	19-11-2018 (Dy. No. 38036)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1)	COA of API	Copy of COA for Cinacalcet hydrochloride from M/s Enaltec Labs Pvt. 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.	Photocopy of GMP Certificate No. 6078745 for Alembic Pharmaceuticals Limited, India issued by Food and Drugs Administration, Maharashtra, India is submitted. Valid till 05-12-2018.
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 Invoice submitted by the firm confirms import of 360.1grams Cinacalcet hydrochloride via DHL. Batch no. is mentioned in invoice. Invoice is not ADC 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

Evaluation by PEC:

- Invoice is not ADC attested.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Cinacal 30mg & 60mg Tablets (Cinacalcet as HCl) Tablets by M/s. Kaizen Pharmaceuticals, Pvt. Ltd., Bin Qasim, Karachi.

Reference No: F.13-11/2017-PEC(Pt) dated 16th January, 2019.
Investigation Date and Time: 28th February, 2019 (Forenoon).
Investigation Site: Factory premises of M/s. Kaizen Pharmaceuticals, (Pvt.), Ltd., Plot#E-127, E-128 & E-129, North Western Industrial Zone, Bin Qasim, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Kaizen Pharmaceuticals, (Pvt.) Ltd., Bin Qasim, Karachi for registration of Cinacal 30mg & 60mg (Cinacalcet as HCl) 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. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
2. Dr. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board, Islamabad.
3. Dr. Kirshan Das, Assistant Director, DRAP Office, 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:

CINACAL 30MG & 60MG TABLETS

Sr. No.	Question	Observation by panel
1	Do you have documents confirming the import of API ?	The firm has imported 50g batch No. (EL-03/A100/16001) Cinacalcet hydrochloride via DHL on 22-02-2017 and 360.1g batch No. (EL-03/A100/16002) also through DHL on 28-02-2017 from M/s. Enaltec Lab, (Pvt) Ltd., India

Sr. No.	Question	Observation by panel
		vide in indenter Biofar, Karachi. The firm has got license No. 3445 dated 05-12-2018 for 360.1g after the laps of 22 months which is not a proper procedure.
2	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification program 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 working standard batch No. (EL/IRS/A100/16/004), however, any impurity standard has not been imported. As per COA of the API there are two known impurities in the API.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificate of analysis for the API and working standards of API. Two batches of working standards have been imported by the firm of which one was expired in June, 2017 while other in September, 2018. The firm has been conducting analysis with expired working standard of the API.
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 non-specific GMP certificate of the manufacturer issued by Food & Drug Administration, Maharashtra, India.
6	Do you use API manufacturer method of testing?	The firm has used API manufacturer method for Assay only which is an isocratic method, however, the method for related substances which is gradient method has not been used to qualify / quantify the related substances.
7	Do you have stability studies reports on API?	The firm has stability studies reports on API showing no value against the impurities (A&B).
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, however, no degradation products have been found as per stability data provided for three API batches.
9	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities in the API, however, this method has not been used.
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of the API, working standard of the API, however, there is no quantity of any impurity as no impurity has been imported by the firm.
11	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients. The excipients include Avicel PH 102 (BP), PVP-K30 (USP), Aerosil-200 (USP), Magniesium Sterate (BP), Pregelatinized Starch (USP), Crospovidone (BP) and SheffCoat.
12	Do you have documents confirming the import of the used excipients?	All the excipients have been purchased locally; however, their COAs are available with the firm.
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 Cinacal (Cinacalcet) 30mg & 60mg tablets.
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 (Mimpara, manufactured by M/S. Amgen, USA).
16	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies only 60mg tablets in comparison to the innovator product (Mimpara 60mg tablets) while employing FDA guidance document for comparative dissolution profile. The firm

Sr. No.	Question	Observation by panel
		formulation have comparable dissolution profile with that of the innovator product. Firm has not performed any comparative dissolution profile study on 30mg tablets. Moreover, the method used for assay in dissolution studies is spectrophotometeric which needs to be validated.
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 whereas the analytical activities are performed in routine QC lab.
18	Do you have necessary equipment available in product development section for development of API tablets?	The firm has necessary equipment for product development in product development section however Cinacal tablets manual work (mixing in poly bag, wet massing in tray) and production equipment (compression machine, tray dryer, coating pan and blister machine) have been used.
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 some qualified staff in product development section however, needs to be improved in all respects.
22	Have you manufactured three stability batches for the stability studies of Cinacal tablets as required?	The firm has manufactured three stability batches for the accelerated and real time stability studies of Cinacal tablet Cinacal Tablet 30mg (Batch No. TF-01, TF-02 and TF-03 each of 1000 tablets) Cinacal Tablet 60mg (Batch No. TF-01, TF-02 and TF-03 each of 1000 tablets). The tablets are packed in Alu Alu blisters with pack size of 10's.
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 have been available with the firm.
25	Do you have protocols for stability testing of stability batches?	The firm has 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 the method for testing stability batches. The method is based on assay method of API provided by API manufacturer. The method is isocratic in non-selective / specific hence cannot quantify the impurities (degradation products).
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?	Validation is done for the assay method. However, the method is non-stability indicating.
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 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 analysis is not stability indicating.
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	The firm showed the audit trail reports on API and finished

Sr. No.	Question	Observation by panel
	and finished product testing?	product.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches only. Degradation products have not been procured nor studied.
33	Do you have stability batches kept on real time 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. 12 months studies have been performed on the first batch whereas, the rest two have been studied for 09 months. Significant variation i.e. > 5% degradation has been found for all the three batches upto three months in the accelerated testing. The real time studies upto 9 months also show degradation about 6% for all three trail batches. 1% more degradation has been found in another 3 months (12 months study) for the first trial batch (Batch#TF-01).
34	Do you have valid calibration status for the equipment used in the production and analysis of API and tablets?	The firm has valid calibration status for the equipment used in Cinacal 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. More stability chambers are required for future studies.
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. Significant change has been found for all the three trial batches in accelerated stability testing at three months. The firm has continued real time stability testing. The 12 months study on trial batch (TF-01) show more than 7% degradation.
2. The firm is using non-stability indicating method therefore, the extent of actual degradation in the trial batches could not be determined.
3. The firm has conducted comparative dissolution profile on 30mg tablets with innovator tablets (Mimpara, 30mg tablets, Manufactured by M/S. Amgen, USA) and have used an expired API working standard for analysis at various time points.

Recommendations:

1. Keeping in view the above facts the genuineness / authenticity of stability data submitted by the firm for registration of Cinacal 30mg & 60mg Tablets (Cinacalcet as HCl) Tablets are not verifiable.
2. Since > 7% degradation has already been found for one batch at 12 months real time stability studies, although using non-stability indicated method which clearly indicate that the product is unstable and extrapolated value of degradation will be outside the product specifications (Assay limit 90% - 110%) even using non-stability indicating method.
3. The firm must re-design / conduct their studies with proper formulation and testing program using authentic reference standards and stability indicating method under the guidance of proper product development staff.

Note: The firm has also shown their interest to re-design the whole study.

Decision: Registration Board rejected the application for registration of Cinacal Tablets 30mg & Cinacal Tablets 60mg (Cinacalcet (as hydrochloride)) by M/s. Kaizen Pharmaceuticals (Pvt.) Ltd; Plot No. E-127, E-128 & E-129 North Western Industrial Zone, Bin Qasim, Karachi based on the observations in the Report on Investigation of Authenticity / Genuineness of data for said products. Following are the observations:

1. **Significant change has been found for all the three trial batches in accelerated stability testing at three months. The firm has continued real time stability testing. The 12 months study on trial batch (TF-01) show more than 7% degradation.**
2. **The firm is using non-stability indicating method therefore, the extent of actual degradation in the trial batches could not be determined.**
3. **The firm has conducted comparative dissolution profile on 30mg tablets with innovator tablets (Mimpara, 30mg tablets, Manufactured by M/S. Amgen, USA) and have used an expired API working standard for analysis at various time points.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1679.	M/s Global Pharmaceuticals (Pvt.) Ltd, Plot No. 204-205,, Industrial Triangle, Kahuta Road, Islamabad.	Promig plus tablets 375mg/20mg Each modified release tablet contains: Naproxen…….375mg Esomeprazole as magnesium…… 20mg (NSAID/Proton pump inhibitor) (Innovator's Specifications)	Form 5-D Dairy No. 27397 dated 09-08-2018 Rs.50,000/- 60's As per DRAP's pricing policy	Vimovo tablets approved by USFDA

STABILITY STUDY DATA			
Drug	Promig plus tablets 375mg/20mg		
Name of Manufacturer	M/s Global Pharmaceuticals (Pvt.) Ltd, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad.		
Manufacturer of API	Naproxen: M/s Zhejiang Tianxin Pharmaceutical Co., Ltd., Tiantai, Zhejiang, China. Esomeprazole magnesium: M/s Metrochem API Private Limited, Telnagana State , India		
API Lot No.	Naproxen: NX1604301 Esomeprazole magnesium: ESM/1707301		
Description of Pack (Container closure system)	HDPE Bottle with Silica gel, heat induction seal & child resistant closure.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,6 months Real Time: 0,3,6 months		
Batch No.	PPT-01	PPT-02	PPT-03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	08-2017	08-2017	08-2017
Date of Initiation	15-09-2017	15-09-2017	15-09-2017
No. of Batches	03		
Date of Submission	09-08-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
i.	COAs of API	Submitted
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.	**Naproxen:** Copy of GMP Certificate (Certificate#. ZJ20140007) issued by SFDA to M/s Zhejiang Tianxin Pharmaceutical Co., Ltd., Tiantai, Zhejiang, China, valid upto 26-1-2019. **Esomeprazole magnesium:** Copy of GMP

		Certificate (Certificate#. L. Dis. No. 428/A2/2017) issued by DCA Government of Telangana to M/s Metrochem API Private Limited, Telnagana State, India and valid upto February, 2018.
iii.	Protocols followed for conduction of stability study and details of tests.	Submitted
iv.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Submitted
v.	Documents confirming import of API etc.	**Esomeprazole magnesium:** Copy of license to import raw material of Esomeprazole magnesium (25Kg) issued by Assistant Director I&E Islamabad, to the M/s Global Pharmaceuticals (Pvt.) Ltd., to be used solely in the manufacture of their registered product "Esmazole tablet (Reg.# 056279)." **Naproxen:** Copy of license to import drug Naproxen base (3Kg) for clinical, trial examination, test for analysis issued by Assistant Director I&E Islamabad, to the M/s Global Pharmaceuticals (Pvt.) Ltd.
vi.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Submitted
vii.	Commitment to continue real time stability study till assigned shelf life of the product.	Submitted
viii.	Commitment to follow Drug Specification Rules, 1978.	Submitted

REMARKS OF EVALUATOR

i. Firm has submitted 6 months of Accelerated & Long term stability data.
ii. Firm has submitted that Esomeprazole drug layer is applied via coating and they have taken 6% additional quantity of Esomeprazole focusing the loss in coating.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1680.	M/s Global Pharmaceuticals (Pvt.) Ltd, Plot No. 204-205,, Industrial Triangle, Kahuta Road, Islamabad.	Promig plus tablets 500mg/20mg Each modified release tablet contains: Naproxen…….500mg Esomeprazole as magnesium…… 20mg (NSAID/Proton pump inhibitor) (Innovator's Specifications)	Form 5-D Dairy No. 27398 dated 09-08-2018 Rs.50,000/- 60's As per DRAP's pricing policy	Vimovo tablets approved by USFDA -

STABILITY STUDY DATA

Drug	Promig plus tablets 500mg/20mg		
Name of Manufacturer	M/s Global Pharmaceuticals (Pvt.) Ltd, Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad.		
Manufacturer of API	Naproxen: M/s Zhejiang Tianxin Pharmaceutical Co., Ltd., Tiantai, Zhejiang, China. Esomeprazole magnesium: M/s Metrochem API Private Limited, Telnagana State , India		
API Lot No.	Naproxen: NX1604301 Esomeprazole magnesium: ESM/1707301		
Description of Pack (Container closure system)	HDPE Bottle with Silica gel, heat induction seal & child resistant closure.		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,6 months Real Time: 0,3,6 months		
Batch No.	PPT-01	PPT-02	PPT-03
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	08-2017	08-2017	08-2017
Date of Initiation	08-09-2017	08-09-2017	08-09-2017
No. of Batches	03		
Date of Submission	09-08-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
i.	COAs of API	Submitted
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.	**Naproxen:** Copy of GMP Certificate (Certificate#. ZJ20140007) issued by SFDA to M/s Zhejiang Tianxin Pharmaceutical Co., Ltd., Tiantai, Zhejiang, China, valid upto 26-01-2019. **Esomeprazole magnesium:** Copy of GMP Certificate (Certificate#. L. Dis. No. 428/A2/2017) issued by DCA Government of Telangana to M/s Metrochem API Private Limited, Telnagana State, India and valid upto February, 2018.
iii.	Protocols followed for conduction of stability study and details of tests.	Submitted
iv.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Submitted
v.	Documents confirming import of API etc.	**Esomeprazole magnesium:** Copy of license to import raw material of Esomeprazole magnesium (25Kg) issued by Assistant Director I&E Islamabad, to the M/s Global Pharmaceuticals (Pvt.) Ltd., to be used solely in the manufacture of their registered product "Esmazole tablet (Reg.# 056279)." **Naproxen:** Copy of license to import drug

		Naproxen base (3Kg) for clinical, trial examination, test for analysis issued by Assistant Director I&E Islamabad, to the M/s Global Pharmaceuticals (Pvt.) Ltd.
vi.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Submitted
vii.	Commitment to continue real time stability study till assigned shelf life of the product.	Submitted
viii.	Commitment to follow Drug Specification Rules, 1978.	Submitted

REMARKS OF EVALUATOR

iii. Firm has submitted 6 months of Accelerated & Long term stability data.

iv. Firm has submitted that Esomeprazole drug layer is applied via coating and they have taken 6% additional quantity of Esomeprazole focusing the loss in coating.

Report on Inspection of Authenticity / Genuineness of data submitted for registration of Promig Plus 500mg/20mg (Naproxen …..500 mg + Esomeprazole……20 mg) and Promig Plus 375mg/20mg (Naproxen …..375 mg + Esomeprazole……20 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: 1st (Morning), 13th (Morning) and 14th (Morning) March,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

Promig Plus 500mg/20mg (Naproxen …..500mg + Esomeprazole……20mg) Tablets and Promig Plus 375mg/20mg (Naproxen …..375mg + Esomeprazole……20 mg) Tablets with following composition:

Promig Plus 500mg/20mg Tablets

Each modified release tablet contains:-

Naproxen ……500 mg

Esomeprazole Magnesium equivalent to Esomeprazole……20mg

Promig Plus 375mg/20mg Tablets

Each modified release tablet contains:-

Naproxen ……....375mg

Esomeprazole Magnesium equivalent to Esomeprazole……20mg

Chairman Registration Board constituted following 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 findings/verification inspection are summarized as under:

Detail of Inspection:

<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 of API including approval from DRAP?</td><td>Naproxen
Invoice Number: 16TXI-164
ADC attestation date: 05.08.2016
Exporter/Manufacturer: M/s Zhejaing Tianxin Pharmaceutical Co. Ltd. No.215, Fengze Road, Tiantai County, Zhejiang Province 317200, China.
Batch No. NX 1604301
Manufacturing Date: 21.04.2016
Expiry Date: 20.04.2019
Quantity: 03 kg
Esomeprazole Magnesium
Invoice Number: AE/17/022
ADC attestation date: 07-08-2017
Exporter: M/s Metrochem API Private Ltd. Flat No.302, Bhanu Enclave, Sunder Nagar Erragadda,Hyderabad-500038, T.S India
Manufacturer: M/s Metrochem API Private Ltd. Plot No. 62/C/6, Pipe line road, phase-1IDA Jeedimetla, Hyderabad-500, Telangana State, India
Batch No. ESM/1707301
Mfg. Date: July-2017
Exp. Date: June-2022
Quantity: 25Kg (The quantity was already in use in manufacturing of commercial batches of registered product Esmazole Tablet 40mg (Esomeprazole).</td></tr>
<tr><td>2.</td><td>What was the rationale behind selecting the particular manufacturer of API?</td><td>Naproxen
The firm has submitted a comparison sheet showing different parameters to compare among 3 different API sources namely:
a. M/s Vervain Pharma-Chem India
b. M/s Wellona Pharmaceutical Ltd. India
c. M/s Zhejiang Tianxin Pharmaceutical Co. China
M/s Zhejiang Tianxin Pharmaceutical Co. Ltd. was selected on the basis of Valid GMP, COA, good impurity profile, and good client list of API manufacture contains International and Local client and Stability Data (Accelerated and Real Time) as per requirement. The firm is already using the “Naproxen sodium” from the same suppliers.
Esomeprazole Magnesium
The firm has submitted that M/s Metrochem API Private Ltd. Flat No.302, Bhanu Enclave, Sunder Nagar Erragadda,Hyderabad-500038, T.S India is their regular supplier and having Valid GMP by the relevant regulatory authority.
The selection of vendor was discussed in detail in the light of GMP guidelines and firm was advised to devise a comprehensive S.O.P covering more parameters in details for the purpose. There should be a detailed report/study for such prequalification studies.</td></tr>
<tr><td>3.</td><td>Do you have documents confirming the import of reference standard and impurity standards?</td><td>The firm imported following reference standards:
Naproxen:
<table>
<tr><th>Name of product</th><th>Source</th><th>Batch No.</th><th>Qty</th><th>Invoice No.</th><th>Mfg. date</th><th>Exp. date</th></tr>
<tr><td>Working Standard</td><td>M/s Zhejiang Tianxin</td><td>1112106</td><td>1 gm</td><td>16TXI-164</td><td>06.2. 2015</td><td>05.02. 2017</td></tr>
</table></td></tr>
</table>

		<table><tr><td></td><td>Pharmaceutical Co. Ltd.</td><td></td><td></td><td></td><td></td><td></td></tr></table> The firm has developed tertiary working standard of Naproxen from secondary standards provided by the Manufacturer/ source for Naproxen. **Esomeprazole Magnesium:** Firm has imported primary standard from which they have and impurities as per details below: <table><tr><th>Name of product</th><th>Source</th><th>Batch No.</th><th>Qty</th><th>Invoice No.</th><th>Mfg. date</th><th>Exp. date</th></tr><tr><td>Esomeprazole primary reference standard</td><td>USP</td><td>G0I290</td><td>10 mg</td><td>783 Purchased via Cavax Enterprises</td><td>-</td><td>-</td></tr><tr><td>Omeprazole Sulphone</td><td>As above</td><td>OP-IMP-E/WS-01/17</td><td>20 mg</td><td>Purchased via NEON Chemicals, Pakistan</td><td>July, 2017</td><td>June, 2018</td></tr><tr><td>Omeprazole N-oxide</td><td>As above</td><td>OP-IMP-E/WS-01/17</td><td>20 mg</td><td>As above</td><td>July, 2017</td><td>June, 2018</td></tr></table>
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: **Neproxen** ✓ Neproxen (API) B. No. NX1604301 ✓ Neproxen reference standard B.No.1112106 **Esomeprazole Magnesium** ✓ Esomeprazole Magnesium (API) B. No. ESM/1707301 ✓ Esomeprazole Magnesium Primary Standard from USP, B. No. G0I290 ✓ Impurity Standard Omeprazole Sulphone, B.No. OP-IMP-E/WS-01/17 ✓ Impurity Standard Omeprazole N-oxide, B.No. OP-IMP-E/WS-01/17
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	**Neproxen** The firm has submitted copy of GMP certificate No: ZJ20140007 in the name of Manufacturer that is "M/s Zhejiang Tianxin Pharmaceutical Co. Ltd. No.215, Fengze Road, Tiantai County, Zhejiang Province 317200, China." of **Neproxen** by the Certifying Authority of "China Food & Drugs Administration, China." Issued on: 27-01-2014 Valid up to: 26-01-2019 **Esomeprazole Magnesium** The firm has submitted copy of GMP certificate No: L.Dis.No.428/A2/2017 in the name of Manufacturer that is "M/s Metrochem API Private Ltd. Unit-I, Plot No.62/C/6, pipeline road, phase-1, IDA Jeedimetla, Hyderabad-500055, Telangana State, India for source of **Esomeprazole Magnesium** by the Certifying Authority of "Drug Control Administration, Government of Telangana (India)" Issued on: 02-02-2017 Valid upto: 01 year from the date issue (01-02-2017).
6.	Do you use API manufacturer method of testing for testing API?	The firm has used USP/pharmacopoeial method of testing for testing for the API Naproxen & Esomeprazole Magnesium.

<table>
<tr><td>7.</td><td>Do you have stability studies reports on API?</td><td>Naproxen:
Firm has submitted data of accelerated stability studies data (at 40 C° ± 2 C° & 75 % RH ± 5 %) of three batches 0605104 (Mfg: 3rd May, 2006), 0605105 (Mfg: 5th May, 2006), & 0605106 (Mfg: 6th May, 2006), up to 6 months and for real time (at 30 C° ± 2 C° & 60 % RH ± 5 %) data up to 36 month, conducted by the API manufacturer “M/s Zhejiang Tianxin Pharmaceutical Co. Ltd. No.215, Fengze Road, Tiantai County, Zhejiang Province 317200, China. for API namely Neproxen. The data submitted by the API manufacturers lies within the limits for the assay, loss on drying & related substances.
<u>Esomeprazole Magnesium:</u>
Firm has submitted data of three batches ESM/A/200807076 (Mfg.: July, 2008), ESM/A/200807077 (Mfg.: July, 2008), & ESM/A/200807078 (Mfg.: July, 2008), for accelerated stability studies (at 40 C° ± 2 C° & 75 % RH ± 5 %) up to 6 months and for real time data (at 30 C° ± 2 C° & 60 % RH ± 5 %) up to 60 month, conducted by the API manufacturer “M/s Metrochem API Private Ltd. Plot No. 62/C/6, Pipe line road, phase-1IDA Jeedimetla, Hyderabad-500, Telangana State, India for API namely Esomeprazole Magnesium. The data submitted by the API manufacturers lies within the limits for the Assay water & impurities.</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 studies of the API verifying the determination of impurities, degradation products as per USP/pharmacopoeial specifications.</td></tr>
<tr><td>9.</td><td>Do you have method for quantifying the impurities in the API?</td><td>The firm stated that they have used the USP testing method for quantifying the impurities in the API Naproxen (by using chromatographic purity test) and Esomeprazole Magnesium.</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="2">1</td><td rowspan="2">Naproxen</td><td rowspan="2">NX1604301</td><td rowspan="2">3kg</td><td>Raw material Testing</td><td>10g</td><td>2990gm</td></tr>
<tr><td>Three Stability Batches STRNGHTH 500/20 mg PPT-01, PPT-02,PPT-03 STRNGHTH 375/20 mg PPT-01, PPT-02,PPT-03</td><td>2625g</td><td>365gm</td></tr>
<tr><td>2</td><td>Esomeprazole magnesium</td><td>ESM/1707301</td><td>0.5kg</td><td>Three Stability Batches STRNGHTH 500/20 mg PPT-01, PPT-02,PPT-03 STRNGHTH 375/20 mg PPT-01, PPT-02,PPT-03</td><td>143.4g</td><td>356.6gm</td></tr>
</table></td></tr>
</table>

		3 | Naproxen (Working. Standard) | 1112106 | 1 g | Raw material Testing | 100mg | 990mg 4 | Omeprazole Sulphone | OP-IMP-E/WS-01/17 | Approx: 20mg | Finished product | -------- | Approx: 20mg 5 | omeprazole N oxide | OP-IMP-E/WS-01/17 | Approx: 20mg | Finished product | --------- | Approx: 20mg
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# | EXCIPIENT NAME | Grade** 1 | PVP-K30 | Pharmaceutical 2 | Crosscarmellose Sodium | Pharmaceutical 3 | Talcum | Pharmaceutical 4 | Magnesium Stearate | Pharmaceutical 5 | Aerosil 200 | Pharmaceutical 6 | Eudragit L100 | Pharmaceutical 7 | Triacetin | Chemical 8 | Sodium Hydroxide | Analytical 9 | Tabcoat clear | Pharmaceutical 10 | Titanium Dioxide | Pharmaceutical 11 | Polyethylene Glycol 400 | Pharmaceutical 12 | HPMC E5 | Pharmaceutical 13 | Propyl paraben | Pharmaceutical 14 | Methyl paraben | Pharmaceutical 15 | Ethanol | Pharmaceutical
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. **Remarks:** a) The firm has not performed complete tests for verifying the quality of excipients. b) The firm shows COA of Talcum with no test of Asbestos which is a cancer causing agent.
14.	Do you have written and authorized protocols for the development of Promig Plus 500mg/20mg Tablet & Promig Plus 375mg/20mg Tablet (Neproxen+Esomeprazole Magnesium)?	The firm has written and authorized protocols for the development of Promig Plus 500mg/20mg Tablet & Promig Plus 375mg/20mg Tablet. But submitted documented was not in accordance with ICH Q-8 which actually 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 Vimovo Tablet approved by EMA.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies against the Vimovo Tablet 500 mg/20 mg (B# AAAN) approved by EMA. However, the studies seems improvement for example the firm has used 6 units for both test and reference products instead of 12 as recommended in USFDA Guidance for Industry: Dissolution testing of immediate release solid oral dosage form.
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.
18.	Do you have necessary equipment available in product development section for development of Promig	The firm has following necessary equipment in R & D section for the development of Promig Plus 500mg/20mg Tablet and 375mg/20mg Tablet.

	Plus 500mg/20mg Tablet & Promig Plus 375mg/20mg Tablet?	**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-339/03-16 | 20-08-2017 | 20-08-2018 Precision Balance | GL/R&D/678 | TX-300/Akira-Japan | 300gm | R&D | IQ-249/03-15 OQ-250/03-15 | 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/Instrumend-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/034 | R1-201/Raxell-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 / Instrumends | - | 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 Promig Plus 500mg/20mg Tablet Promig Plus 375mg/20mg Tablet?	The firm has manufactured following three stability batches for the stability studies of Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg Tablet: **S. No.** | **Stability Batchs** | **Batch Sizes** Promig Plus 500mg/20mg Tablet a. | PPT-01 | 1000 tablets b. | PPT-02 | 1000 tablets c. | PPT-03 | 1000 tablets Promig Plus 375mg/20mg Tablet d. | PPT-01 | 1000 tablets e. | PPT-02 | 1000 tablets f. | PPT-03 | 1000 tablets
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: **Batch Sizes** | **Tablets for real time studies** | **Tablets for accelerated studies** | **Total packs per batch required** 1000 tablets | 420 Tablets OR | 360 Tablets OR | 780 Tablets OR

		<table><tr><td></td><td>7 Packs</td><td>6 Packs</td><td>13 Packs</td></tr></table> Batch size = 1000 Tablets, Pack Size 60'S
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 for conducting stability studies on batches of applied formulation at 30 C^o $\pm$ 2 C^o & 65 % RH $\pm$ 5 % 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 its own developed 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: i. Specificity ii. Precision a. Repeatability b. Intermediate Precision iii. Accuracy iv. Linearity v. Robustness vi. System Suitability vii. Limit of Quantification/Detection viii. Range
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 developed by them hence no method transfer studies are required.
28.	Do you have documents confirming the qualifications of equipment/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 as per details under question No:18.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating for stability testing of their finished product, the data sheet submitted by firm verifies the testing of impurity on samples kept on stability studies. The firm has conducted impurity testing at one time at 6^{th} month time point it was discussed to conduct the impurity testing at initial and end time point (i.e., at 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 Promig Plus 500mg/20mg Tablet and Promig Plus 375mg/20mg. The HPLC used for the stability studies is 21-CFR compliant. 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 Promig Plus 500mg/20mg tablets 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 remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches as per following details:

		<table><tr><th>S#</th><th>Product Name</th><th>Batch No.</th><th>Total packs</th><th>Sample for Accelerated study</th><th>Sample for Real Time Study</th><th>Remaining Packs</th></tr><tr><td rowspan="3">1</td><td rowspan="3">Promig plus 500/20mg Tablet</td><td>PPT-01</td><td>14</td><td>6</td><td>7</td><td>2</td></tr><tr><td>PPT-02</td><td>16</td><td>6</td><td>7</td><td>2</td></tr><tr><td>PPT-03</td><td>15</td><td>6</td><td>7</td><td>2</td></tr><tr><td rowspan="3">2</td><td rowspan="3">Promig plus 375/20mg Tablet</td><td>PPT-01</td><td>15</td><td>6</td><td>7</td><td>2</td></tr><tr><td>PPT-02</td><td>15</td><td>6</td><td>7</td><td>2</td></tr><tr><td>PPT-03</td><td>15</td><td>6</td><td>7</td><td>2</td></tr></table>
33.	Do you have stability batches kept on stability testing?	The firm has completed the accelerated stability testing on the three stability batches of Promig Plus 500mg/20mg Tablet and 375mg/20mg Promig Plus Tablet. Also the firm has completed the real time stability testing up to 12 months on all three batches. However, in real time studies the testing at 9th month time point is missing.
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 production and analysis of Promig Plus 500mg/20mg Tablet and 375mg/20mg Promig Plus Tablet 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 date-wise data for every next hour of temperature and humidity conditions of stability chambers used for accelerated and real time studies.
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.
37.	Applied technology of drug layering for Esomeprazole in which Drug is loaded via coating solution on the core tablet of Naproxen.	The firm stated that drug layer of Esomeprazole was applied on the enteric coated Naproxen tablet (core) through manual coating technique i.e. coating pan and spray gun.
38.	Justification of 6% overage of esomeprazole in master formulation (Which is required to be based on study/scientific rationale) for which firm has stated that additional quantity of Esomeprazole was used focusing the loss of coating.	In order to fix this percentage the firm performed several trials. First the firm applied 100% esomeprazole drug layer as dispersion in IPA, the results showed remarkable reduction in esomeprazole assay to 26.89%. The possible loss was due to use of esomeprazole as dispersion and its loss during coating process. Then they decided to change the coating solution composition and applied esomeprazole drug layer as solution in ethanol. Keeping in view of the drug loss during coating the firm performed three consecutive trials with 120% esomeprazole in coating solution in ethanol. The first trial B# T-012Q (part I) yield a results 111.13%. The same formulation was again trialed for two times B#T-012Q (Part II), B#T-012Q (Part III) with more precaution and the results produced were 115.69% and 116.38%. The average loss in all three 03 trials was 6%. Based on the average loss a trial T-026 with 106% Esomeprazole in coating solution in ethanol was conducted and the results achieved were 101.37%. Based on these trials 6% overage was made as part of master formulation.

Conclusions & Recommendations:

1. On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of 375mg/20mg Promig Plus Tablet and Promig Plus 500mg/20mg tablets is verifiable to a satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suitable for the manufacturing of 375mg/20mg Promig Plus Tablet and Promig Plus 500mg/20mg tablets, therefore, the panel

recommends the registration of Promig Plus 500mg/20mg tablets in the name of the manufacturer.

Decision: Registration Board decided to approve registration of "Promig plus tablets 500mg/20mg & Promig Plus tablets 375mg/20mg by by M/s. Global Pharmaceuticals (Pvt.) Ltd., Islamabad. 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.

b. Exemption from onsite verification of stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1681.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 km Sheikhupura Road Faisalabad	Elixa 2.5mg Tablets Each film coated tablet contains: Apixaban …2.5mg Antithrombotic agent (Direct factor Xa inhibitor) Manufacturer's Specifications.	Form 5-D Dairy No. 184 dated 07-12-2015. Rs.50,000/- dated 28-11-2016.(Challan#0290354) Rs.5040/- / 60's.	ELIQUIS (apixaban) film coated tablets 2.5mg by M/s Bristol-Myers Squibb Company (USFDA approved) The firm was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate

STABILITY STUDY DATA			
Drug	Elixa 2.5mg Tablets (Apixaban)		
Name of Manufacturer	M/s Saffron Pharmaceuticals (Pvt) Ltd.		
Manufacturer of API	M/s Glenmark Pharmaceuticals Limited, Plot#3109, GIDC, Industrial estate, Ankleshwar city Ankleshwar-393002 District, Bharuch, Gujrat state India.		
API Lot No.	801609708		
Description of Pack (Container closure system)	Alu Alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 9 months		
Frequency	Accelerated: 0,3,6 (months) Real Time: 0,3,6, 9, 12, 18, 24 (months)		
Batch No.	T-004	T-003	T-002
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2017	12-2017	08-2017
Date of Initiation	22-01-2018	22-01-2018	13-10-2017
No. of Batches	03		
Date of Submission	21-01-2019 (Dy. No. 2685)		

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 dapagli Apixaban 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.	Copy of GMP certificate issued by Food and Drugs control administration, Gujrat state India to, Glenmark Pharmaceuticals Limited. Plot#3109, GIDC, Industrial estate, Ankleshwar city Ankleshwar-393002 District, Bharuch, Gujrat state India valid up to 18-08- 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 07-02-2017 confirming import of 0.057 Kg Apixaban. • Batch no. 801609708 • Invoice no. 2006004973 • Firm has submitted copy of Form-3 confirming import of API from M/s Glenmark pharmaceuticals Ltd. • Firm has submitted copy of Form-7 confirming batch no of API i.e. 801609708.
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 Saffaldi Tablet 400mg (Sofosbuvir), which was conducted on 8th January, 2018 and was presented in 279th meeting of Registration Board held on 28th February-2nd March, 2018. Following observations were reported in the report: i. The HPLC software is 21CFR Compliant. ii. Firm has shown all Audit trail reports. 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).	• Firm has submitted ADC attested copy dated **07-02-2017** confirming import of 0.057 Kg **Apixaban**. Batch no. 801609708 Invoice no. 2006004973 • Firm has submitted copy of Form-3 confirming import of API from M/s Glenmark pharmaceuticals Ltd. • Firm has submitted copy of Form-7 confirming batch no of API i.e. 801609708.
3.	Documents for the procurement of reference standard and impurity standards.	• Firm has submitted declaration from API manufacturer regarding dispatiching of Apixaban working standard to M/s Saffron Pharmaceuticals. • Quantity of working standard imported by the firm is n100mg Batch#WD18801.01.
4.	Approval of API/ DML/GMP	Copy of GMP certificate issued by Food and Drugs control

<table>
<tr><td></td><td>certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>administration, Gujrat state India to, Glenmark Pharmaceuticals Limited. Plot#3109, GIDC, Industrial estate, Ankleshwar city Ankleshwar-393002 District, Bharuch, Gujrat state India valid up to 18-08- 2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• Firm has submitted vendor evaluation form which confirms the SOPs for vendor qualification. However, it is not filled by either the manufacturer of API nor by the applicant.</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 submitted by the firm.
• COA of working 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 # RD/GN/SP/002).
• Firm has submitted SOPs for stability study protocol. (document # RD/GN/SP/001)</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>Remaining Quantities of tablets</th></tr><tr><td>T-004</td><td>264</td></tr><tr><td>T-003</td><td>264</td></tr><tr><td>T-002</td><td>176</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 manual records of stability chamber#3 for long term stability from 05-09-2017 to29-12-2017
• Firm has submitted record of digital data logger for temperature and humidity monitoring control for real time stability study. The time period was from 01-01-2018 to 27-03-2018.
• Another digital data submitted for long term stability study is from 15-08-2018 to 25-01-2019.
• The data submitted for long term stability study does not cover whole period.
• Firm has not submitted record of digital data logger for temperature and humidity monitoring control for accelerated stability study.</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 Apixaban from M/s Glenmark pharmaceuticals Ltd. has been submitted.</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
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 40°C ± 2°C / 75% ± 5%RH for accelerated studies for 6 months.
• Submitted summary sheet of long term stability study for 3 batches of API is conducted at 25°C ± 2°C / 60% ± 5%RH for long term for 18months.</td></tr>
</table>

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 Dissolution profile of FPP at 3 different mediums i.e HCl buffer pH 1.2, Acetate Buffer pH 4.5, Phosphate Buffer pH 6.8. • However firm did not submit Dissolution profile of reference product at above mentioned mediums thus also firm was unable to calculate the f2 similarity factor.
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:

- Relevant chromatograms and FTIR spectrum, for generated COA of API by M/s Saffron Pharmaceuticals (Pvt) Ltd are not submitted.
- Firm has not submitted dissolution profiles for reference product for CDP. Also, f2 similarity factor shall be calculated and submitted.
- Relevant analytical record of CDP i.e. chromatograms, raw data sheets not submitted by the firm.
- Long term Stability studies of Apixaban as per Zone IV-A conditions from API manufacturer is not submitted. Upon intimation to the firm, the response was, "Required stability data according to Zone-IV-A manufacturer has not provided the data due to current crisis between both the countries; we are continuously having follow up regarding this matter."
- System generated electronic record of stability chambers for temperature and humidity conditions covering the stability study duration is not submitted.

Decision: Registration Board decided to deferred the case for following:

i. **Submission of relevant chromatograms and FTIR spectrum, for generated COA of API by the firm.**
ii. **Submittion of dissolution profiles for reference product for CDP. Also, f2 similarity factor shall be calculated and submitted.**
iii. **Submission of relevant analytical record of CDP i.e. chromatograms, raw data sheets.**
iv. **Submission of long term Stability studies of Apixaban as per Zone IV-A conditions from API manufacturer.**
v. **Submission of system generated electronic record of stability chambers for temperature and humidity conditions covering the stability study duration.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1682.	M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 km Sheikhupura Road Faisalabad	Elixa 5mg Tablets Each film coated tablet contains: Apixaban …5mg Antithrombotic agent (Direct factor Xa inhibitor) Manufacturer's Specifications.	Form 5-D Dairy No. 182 dated 07-12-2015. Rs.50,000/- dated 28-11-2016.(Challan#0290355) Rs.5040/- / 60's.	ELIQUIS (apixaban) film coated tablets 5mg by M/s Bristol-Myers Squibb Company (USFDA approved) The firm was last inspected on 03.10.2018, .wherein the panel recommended the grant of GMP certificate

STABILITY STUDY DATA

Drug	Elixa 5mg Tablets (Apixaban)
Name of Manufacturer	M/s Saffron Pharmaceuticals (Pvt) Ltd.

Manufacturer of API	M/s Glenmark Pharmaceuticals Limited, Plot#3109, GIDC, Industrial estate, Ankleshwar city Ankleshwar-393002 District, Bharuch, Gujrat state India.		
API Lot No.	801609708		
Description of Pack (Container closure system)	Alu Alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 9 months		
Frequency	Accelerated: 0,3,6 (months) Real Time: 0,3,6, 9, 12, 18, 24 (months)		
Batch No.	T-004	T-003	T-002
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	03-2018	09-2017	08-2017
Date of Initiation	18-05-2018	10-10-2017	12-09-2017
No. of Batches	03		
Date of Submission	21-01-2019 (Dy. No. 2684)		

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 dapagli Apixaban 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.	Copy of GMP certificate issued by Food and Drugs control administration, Gujrat state India to, Glenmark Pharmaceuticals Limited. Plot#3109, GIDC, Industrial estate, Ankleshwar city Ankleshwar-393002 District, Bharuch, Gujrat state India valid up to 18-08- 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 07-02-2017 confirming import of 0.057 Kg Apixaban. • Batch no. 801609708 • Invoice no. 2006004973 • Firm has submitted copy of Form-3 confirming import of API from M/s Glenmark pharmaceuticals Ltd. • Firm has submitted copy of Form-7 confirming batch no of API i.e. 801609708.
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 Saffaldi Tablet 400mg (Sofosbuvir), which was conducted on 8th January, 2018 and was presented in 279th meeting of Registration Board held on 28th February-2nd March, 2018. Following observations were reported in the report: i. The HPLC software is 21CFR Compliant. ii. Firm has shown all Audit trail reports. 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).	• Firm has submitted ADC attested copy dated **07-02-2017** confirming import of 0.057 Kg **Apixaban**. Batch no. 801609708 Invoice no. 2006004973 • Firm has submitted copy of Form-3 confirming import of API from M/s Glenmark pharmaceuticals Ltd. • Firm has submitted copy of Form-7 confirming batch no of API i.e. 801609708.
3.	Documents for the procurement of reference standard and impurity standards.	• Firm has submitted declaration from API manufacturer regarding dispatiching of Apixaban working standard to M/s Saffron Pharmaceuticals. • Quantity of working standard imported by the firm is n100mg Batch#WD18801.01.
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, Gujrat state India to, Glenmark Pharmaceuticals Limited. Plot#3109, GIDC, Industrial estate, Ankleshwar city Ankleshwar-393002 District, Bharuch, Gujrat state India valid up to 18-08- 2019.
5.	Mechanism for Vendor pre-qualification	• Firm has submitted vendor evaluation form which confirms the SOPs for vendor qualification. However, it is **not filled** by either the manufacturer of API nor by the applicant.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Certificate of analysis of the API submitted by the firm. • COA of working standard submitted by the firm.
7.	Documents for the procurement of excipients used in product development?	• Firm has submitted documents for procurement of excipients used in product development.
8.	List of qualified staff involved in product development with relevant experience.	• Firm has submitted list of 2 qualified person working in product development section.
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	• Firm has submitted SOP for product design and development protocol (document # RD/GN/SP/002). • Firm has submitted SOPs for stability study protocol. (document # RD/GN/SP/001)
10.	Complete batch manufacturing record of three stability batches.	• Firm has provided complete batch manufacturing record of all the three batches.
11.	Record of remaining quantities of stability batches.	**Batch No** / **Remaining Quantities of tablets** T-004 / 316 T-003 / 212 T-002 / 176

QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	• Firm has submitted manual records of stability chamber#3 for long term stability from 05-09-2017 to29-12-2017 • Firm has submitted record of digital data logger for temperature and humidity monitoring control for real time stability study. The time period was from 01-01-2018 to 27-03-2018. • Another digital data submitted for long term stability study is from 15-08-2018 to 25-01-2019. • The data submitted for long term stability study does not cover whole period. • Firm has not submitted record of digital data logger for temperature and humidity monitoring control for accelerated stability study.
13.	Method used for analysis of API along with COA.	• Method used for analysis of API along with copy of COA for Apixaban from M/s Glenmark pharmaceuticals Ltd. has been submitted.
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 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 40°C ± 2°C / 75% ± 5%RH for accelerated studies for 6 months. • Submitted summary sheet of long term stability study for 3 batches of API is conducted at 25°C ± 2°C / 60% ± 5%RH for long term for 18months.
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17.	Drug-excipients compatibility studies.	• Submitted by the firm.
18.	Record of comparative dissolution data.	• Firm has submitted Dissolution profile of FPP at 3 different mediums i.e HCl buffer pH 1.2, Acetate Buffer pH 4.5, Phosphate Buffer pH 6.8. • However firm did not submit Dissolution profile of reference product at above mentioned mediums thus also firm was unable to calculate the f2 similarity factor.
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:

- Relevant chromatograms and FTIR spectrum, for generated COA of API by M/s Saffron Pharmaceuticals (Pvt) Ltd are not submitted.
- Firm has not submitted dissolution profiles for reference product for CDP. Also, f2 similarity factor shall be calculated and submitted.
- Relevant analytical record of CDP i.e. chromatograms, raw data sheets not submitted by the firm.
- Long term Stability studies of Apixaban as per Zone IV-A conditions from API manufacturer is not submitted. Upon intimation to the firm, the response was, "Required stability data according to Zone-IV-A manufacturer has not provided the data due to current crisis between both the countries; we are continuously having follow up regarding this matter."
- System generated electronic record of stability chambers for temperature and humidity conditions covering the stability study duration is not submitted.

Decision: Registration Board decided to deferred the case for following:

i. **Submission of relevant chromatograms and FTIR spectrum, for generated COA of API by the firm.**
ii. **Submittion of dissolution profiles for reference product for CDP. Also, f2 similarity factor**

shall be calculated and submitted.

iii. **Submission of relevant analytical record of CDP i.e. chromatograms, raw data sheets.**

iv. **Submission of long term Stability studies of Apixaban as per Zone IV-A conditions from API manufacturer.**

v. **Submission of system generated electronic record of stability chambers for temperature and humidity conditions covering the stability study duration.**

Evaluator PEC-XIII

Case No. 01 Registration applications for local manufacturing of (Human) drugs.

a. Deferred cases

1683.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. **Contract Manufacturer:** M/s Bio-Labs (Pvt) Ltd,Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	M- Xone 250mg Injection I/M
	Composition	Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone…….250mg
	Diary No. Date of R& I & fee	Dy. No. 187, 24-04-2017; Rs.50,000/- (24-04-2017)
	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 250mg powder for solution for Injection vials of M/s Roche, UK (MHRA Approved)
	Me-too status	Rocephin of M/s Roche
	GMP status	M/s Iceberg: Last inspection 04-11-2016. M/s Bio-Labs: Last inspection report dated 05 & 06-12-2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s AstellasPharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have **not** been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s **Astellas** Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis.

		• GMP inspection of M/s Iceberg was conducted on 05-12-2018 and the report concludes: "Production of the firm shall remain suspended till recommendation by panel & subsequent approval by theCLB.**"**
	Decision: Deferred for updated status of GMP of the applicant firm from QA & LT division as inspection report submitted by the firm does not conclude GMP compliant status.	
1684.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. **Contract Manufacturer:** M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	M- Xone 500mg Injection I/M
	Composition	Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone..500mg
	Diary No. Date of R& I & fee	Dy. No. 186, 24-04-2017; Rs.50,000(24-04-2017)
	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 powder for solution for Injection vials by Roche (MHRA Approved)
	Me-too status	Rocephin by Martin Dow
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs: Last inspection report dated 5 &6th December, 2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s AstellasPharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have **not** been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s **Astellas** Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018**and the report concludes: "Production of the firm shall remain suspended till recommendation by panel and subsequent approval by CLB."

	Decision: Deferred for updated status of GMP of the applicant firm from QA & LT division as inspection report submitted by the firm does not conclude GMP compliant status.	
1685.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. **Contract Manufacturer:** M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	M- Xone 1g Injection I/M
	Composition	Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone…….1g
	Diary No. Date of R& I & fee	Dy. No. 189, 24-04-2017; Rs.50,000/- (24-04-2017)
	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 powder for solution for Injection vials by Roche (MHRA Approved)
	Me-too status	Rocephin by Martin Dow
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs: Last inspection report dated 5 & 6th December, 2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have **not** been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s **Astellas** Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018**and the report concludes: "Production of the firm shall remain suspended till recommendation by panel and subsequent approval by CLB."
	Decision: Deferred for updated status of GMP of the applicant firm from QA & LT division as inspection report submitted by the firm does not conclude GMP compliant status.	
1686.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. **Contract Manufacturer:** M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.

	Brand Name +Dosage Form + Strength	Senofer 20mg/ml Injection
	Composition	Each ml ampoule contains:- Iron (as sucrose)…… 20 mg
	Diary No. Date of R& I & fee	Dy. No. 185, 24-04-2017; Rs.50,000/- (24-04-2017)
	Pharmacological Group	Replenishes Hgb and depleted iron stores
	Type of Form	Form- 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	5ml x 5's & as per PRC
	Approval status of product in Reference Regulatory Authorities.	Venofer Injection by Vifor Pharma (UK MHRA Approved)
	Me-too status	Ferotein-S by Getz venofer of RG
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs: Last inspection report dated 05 & 06-12-2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have **not** been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s **Astellas** Pharma has General Liquid Injection section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018**and the report concludes: Production of the firm shall remain suspended till recommendation by panel and subsequent approval by CLB."
	Decision: Deferred for updated status of GMP of the applicant firm from QA & LT division as inspection report submitted by the firm does not conclude GMP compliant status.	
1687.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. **Contract Manufacturer:** M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	LNTROP-D Injection I/M
	Composition	Each ml contains:- Cholecalciferol …… 5 mg (eq. to 2, 00,000 I.U.)
	Diary No. Date of R& I & fee	Dy. No. 188, 24-04-2017; Rs.50,000/- (24-04-2017)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	"1's, 5's" & As per SRO

	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection (ANSM, France)
	Me-too status	Get D injection of M/s Getz Pharma
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs: Last inspection report dated 5 & 6-12-2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have **not** been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s **Astellas** Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018** and the report concludes: "Production of the firm shall remain suspended till recommendation by panel and subsequent approval by CLB."
	Decision: Deferred for updated status of GMP of the applicant firm from QA & LT division as inspection report submitted by the firm does not conclude GMP compliant status.	
1688.	Name and address of manufacturer / Applicant	M/s Dr. Raza Pharma, Plot # 44- C, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Klary 250mg/ 5ml Dry Suspension
	Composition	Each 5ml contains: Clarithromycin ……..……..….250mg
	Diary No. Date of R& I & fee	Dy.No.17158; 05-10-2017; Rs.20,000(05-10-2017)
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120ml & as per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Claritek 250mg/ 5ml Dry Suspension of M/s Getz Pharma
	GMP status	Last GMP inspection was conducted on 6th August, 2018 & report concludes: "Overall the GMP compliance is satisfactory and the firm is advised to prepare a plan for the rectification of all the

		deficiencies mentioned above at the earliest. They are further directed to immediately get the approval/validation of their layout plan from Licensing Division. The above points were discussed with management and they agreed to rectify at the earliest."
	Previous remarks of the Evaluator	General dry powder suspension section is not available in the firm. Instead dry powder suspension (Cephalosporin) and Dry suspension (Penicillin) is available.
	Previous decision	• Deferred in 285th DRB meeting for following reasons: Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status. • Approved manufacturing facility for "General" dry powder suspension section.
	Evaluation by PEC	• Firm has submitted its last GMP inspection report; dated: 24-01-2019, and the report concludes satisfactory GMP compliance. • General dry powder suspension section is verified through submitted GMP report dated 24-01-2019.
	Decision: Approved	
1689.	Name and address of manufacturer / Applicant	M/s Dr. Raza Pharma, Plot # 44- C, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Klary tablet 500mg
	Composition	Each film- coated tablet contains: Clarithromycin……500mg
	Diary No. Date of R& I & fee	Dy.No.17159; 05-10-2017;Rs.20,000 (05-10-2017)
	Pharmacological Group	Antibacterial (Macrolide)
	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 and 1000's & Rs. 450/-
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Arithro of M/s Novamed Pharmaceuticals (Reg. # 043479)
	GMP status	Last GMP inspection was conducted on 6th August, 2018and the report concludes: "Overall the GMP compliance is satisfactory and the firm is advised to prepare a plan for the rectification of all the deficiencies mentioned above at the earliest. They are further directed to immediately get the approval/validation of their layout plan from Licensing Division. The above points were discussed with management and they agreed to rectify at the earliest."
	Previous remarks of the Evaluator	Firm has General tablet section.
	Previous decision	Deferred in 285th 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 submitted its last GMP inspection report; dated: 24-01-2019, and the report concludes satisfactory GMP compliance.
	Decision: Approved	
1690.	Name and address of manufacturer / Applicant	M/s Dr. Raza Pharma, Plot # 44- C, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Vixime dry suspension 200mg/ 5ml
	Composition	Each 5ml contains: Cefixime (as Trihydrate)……200mg
	Diary No. Date of R& I & fee	Dy.No.17157; 05-10-2017;Rs.20,000 (05-10-2017)

	Pharmacological Group	Cephalosporin (Antibiotic)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml , 90ml, 120ml, 150ml & Rs. 300/-
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Cefspan 200mg Dry Suspension of M/s Barrett Hodgson(Reg. # 024634)
	GMP status	Last GMP inspection was conducted on 6th August, 2018and the report concludes: "Overall the GMP compliance is satisfactory and the firm is advised to prepare a plan for the rectification of all the deficiencies mentioned above at the earliest. They are further directed to immediately get the approval/validation of their layout plan from Licensing Division. The above points were discussed with management and they agreed to rectify at the earliest."
	Previous remarks of the Evaluator	• The official monograph of the applied formulation is available in USP. • Firm has dry powder suspension (Cephalosporin) section.
	Previous decision	Deferred in 285th 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 submitted its last GMP inspection report; dated: 24-01-2019, and report concludes satisfactory GMP compliance.
	Decision: Approved	
1691.	Name and address of manufacturer / Applicant	M/s Dr. Raza Pharma, Plot # 44- C, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Cifa 250mg Dry Suspension
	Composition	Each 5ml contains: Ciprofloxacin ……...250mg
	Diary No. Date of R& I & fee	Dy.No.17156; 05-10-2017; Rs.20,000/- (05-10-2017)
	Pharmacological Group	Quinolones (Antibiotic)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml , 90ml, 120ml, 150ml & Rs. 160/-
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Mytil 250mg Dry Suspension of M/s Wilson (Reg. #027696)
	GMP status	Last GMP inspection was conducted on 6th August, 2018and the report concludes: "Overall the GMP compliance is satisfactory and the firm is advised to prepare a plan for the rectification of all the deficiencies mentioned above at the earliest. They are further directed to immediately get the approval/ validation of their layout plan from Licensing Division. The above points were discussed with management and they agreed to rectify at the earliest."
	Previous remarks of the Evaluator	General dry powder suspension section is not available in the firm. Instead dry powder suspension (Cephalosporin) and Dry suspension (Penicillin) is available.
	Previous decision	Deferred in 285th DRB meeting for following reasons: • Updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.

		• Approved manufacturing facility for "General" dry powder suspension section.
	Evaluation by PEC	• Firm has submitted its last GMP inspection report; dated: 24-01-2019, and the report concludes satisfactory GMP compliance. • General dry powder suspension section is verified through submitted GMP report dated 24-01-2019. • No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications. Diluent shall be as per innovator's product	
1692.	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	Ropol tablets 500mg
	Composition	Each tablet contains: Paracetamol …….....500mg
	Diary No. Date of R& I & fee	Dy. No. 192; 24-04-2017; Rs.20,000 (24-04-2017)
	Pharmacological Group	Non- Narcotic Analgesic
	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	20x10's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Panadol tablet 500mg of M/s GSK (Reg. # 000817)
	GMP status	Last GMP inspection report dated 07-12-2017 with no conclusion.
	Previous remarks of the Evaluator	• A banned excipient called Methylene Chloride is mentioned to be used under the heading of specifications in Annexure-D of the dossier. • 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 and justification of addition of a banned excipient named Methylene Chloride.
	Evaluation by PEC	• Last GMP inspection was conducted **18-07-2018** and the report concludes **grant of GMP certificate**. • An Undertaking is submitted by the firm not to use any banned excipient in any of their proposed formulation. • Firm has General tablet section as mentioned in the submitted section approval letter.
	Decision: Approved	
1693.	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	Macrozith tablet 500mg
	Composition	Each film-coated tablet contains: Azithromycin Dihydrate eq. to Azithromycin.....500mg
	Diary No. Date of R& I & fee	Dy. No. 1040; 22-03-2017;Rs.20,000 (22-03-2017)
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	3's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Azomax tablet 500mg of M/s Novartis Pharma
	GMP status	Last GMP inspection report dated 07-12-2017 with no conclusion.

	Previous remarks of the Evaluator	• A banned excipient called Methylene Chloride is mentioned to be used under the heading of specifications in Annexure-D of the dossier. • 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 and justification of addition of a banned excipient named Methylene Chloride.
	Evaluation by PEC	• Last GMP inspection was conducted **18-07-2018** and the report concludes **grant of GMP certificate**. • An Undertaking is submitted by the firm not to use any banned excipient in any of their proposed formulation. • Firm has General tablet section as mentioned in the submitted section approval letter.
	Decision: Approved	
1694.	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	Valsam tablet 10mg/160mg
	Composition	Each film-coated tablet contains: Amlodipine (as Besylate)…….10mg Valsartan……..160mg
	Diary No. Date of R& I & fee	Dy. No. 3944; 09-03-2017; Rs.20,000/- (09-03-2017)
	Pharmacological Group	Angiotensin II antagonist and calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	14's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge tablet 10mg/160mg of M/s Novartis Pharmaceuticals (USFDA Approved)
	Me-too status	Exforge tablet 10mg/160mg of M/s Novartis Pharma, Pak (Reg. # 047571)
	GMP status	Last GMP inspection report dated 07-12-2017 with no conclusion.
	Previous remarks of the Evaluator	• A banned excipient called Methylene Chloride is mentioned to be used under the heading of specifications in Annexure-D of the dossier. • 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 and justification of addition of a banned excipient named Methylene Chloride.
	Evaluation by PEC	• Last GMP inspection was conducted **18-07-2018** and the report concludes **grant of GMP certificate**. • An Undertaking is submitted by the firm not to use any banned excipient in any of their proposed formulation. • Firm has General tablet section as mentioned in the submitted section approval letter.
	Decision: Approved	
1695.	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 20mg/120mg
	Composition	Each tablet contains: Artemether…….20mg Lumefantrine ……...120mg
	Diary No. Date of R& I & fee	Dy. No.194; 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	2x8's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Approved as **Dispersible tablet**
	Me-too status	Artheget tablet 20mg/120mg of M/s Getz Pharmaceuticals, Pak (Reg. # 042295)
	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. • The applied formulation is approved in WHO prequalified list as dispersible tablet while not applied as dispersible.
	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 and type of dosage form as dispersible tablet is approved in reference regulatory authorities while not applied as dispersible.
	Evaluation by PEC	• Last GMP inspection was conducted **18-07-2018** and the report concludes **grant of GMP certificate**. • In WHO prequalified list of medicines, both type of tablets are available i.e. uncoated as well as dispersible. Firm has applied as uncoated which is approved in WHO. • Firm has General tablet section as mentioned in the submitted section approval letter.
	Decision: Approved	
1696.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals, Plot # 122, Block- A , Phase-V, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	O-Carb oral granules Sachet 40/1100mg
	Composition	Each 4g of oral granules contains: Omeprazole ……..40mg Sodium Bicarbonate……1100mg
	Diary No. Date of R& I & fee	Dy. No.16938; 04-10-2017; Rs.20,000/- (02-10-2017)
	Pharmacological Group	Proton Pump Inhibitor/ Salt solutions (Antacid)
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could **not** be confirmed in the applied strength (Sodium bicarbonate is approved in 1680mg)
	Me-too status	Could **not** be confirmed in the applied strength (Sodium bicarbonate is approved in 1680mg)
	GMP status	Last inspection report conducted on 18-01-2018 recommending renewal of DML.
	Previous remarks of the Evaluator	• The me-too and international evidence in the applied strength could not be confirmed.
	Previous decision	Deferred in 285th DRB meeting for the following reasons: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation by PEC	• Now, the firm has corrected its formulation as

		Omeprazole……40mg Sodium Bicarbonate……..….1680mg • Firm has submitted Rs. 20,000/- and has submitted new Form- 5.
	Decision: Approved	
1697.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23 Km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Phenobarbital Injection 200mg/ ml
	Composition	Each ml contains: Phenobarbital Sodium ……200mg
	Diary No. Date of R& I & fee	Dy.No.17639; 11-05-2018; Rs.20,000 (11-05-2018)
	Pharmacological Group	Barbiturate and derivatives (Anti- epileptic)
	Type of Form	Form -5
	Finished product Specification	B.P.
	Pack size & Demanded Price	1ml x 5 amp, 1ml x 100 ampoules & Rs. 150/- , Rs.250/-
	Approval status of product in Reference Regulatory Authorities	Phenobarbital sodium Injection of M/s Aspen (Australia Approved)
	Me-too status	Phenobarb 200mg/ml of M/s Atco Pharma
	GMP status	Last GMP inspection was conducted on 07-04-2017 and the report concludes renewal of DML.
	Previous remarks of the Evaluator	• Renewal of injectable ampoule (Psychotropic) section was done on 10-12-2014. • Firm has not mentioned whether they have applied as glass ampoules or plastic ampoules while the reference approves glass ampoules.
	Previous decision	Deferred in 283rd DRB meeting with following decision: Registration Board referred the case to QA & LT Division to conduct inspection of the firm. Moreover, the firm needs to clarify the type of container closure system whether they have applied as glass ampoules or plastic.
	Evaluation by PEC	• Firm has submitted its latest GMP report dated: 9th July, 2018 concluding satisfactory GMP compliance with grant of GMP certificate for export purpose. • Firm has clarified the type of primary packaging container as USP Type- I **Glass** Ampoule. • Firm has Liquid Injectable Psychotropic (Vial and ampoule) section as mentioned in the submitted section approval letter.
	Decision: Approved	
1698.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt Ltd, 539-A Sundar Industrial Estate, Raiwind Road ,Lahore
	Brand Name +Dosage Form + Strength	Vergo 24mg Tablet
	Composition	Each tablet Contains: 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.
	Previous remarks of the Evaluator	Tablet Section is approved.
	Previous decision	Deferred in 288th 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 submitted its latest GMP inspection report dated: 29-03-2019 concluding satisfactory level of GMP compliance. • Firm has General Tablet section as mentioned in the submitted GMP inspection report.
	Decision: Approved	

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

Liquid Syrup (General) 10 products/ 10 molecules		
1699.	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	Respect 1mg/ml Oral Solution
	Composition	Each ml contains: Risperidone …… 1mg
	Diary No. Date of R& I & fee	Dy.No.41087; 06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml/ MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities	Risperdal 1mg/ml oral solution by M/s Janssen-Cilag Ltd (MHRA Approved)
	Me-too status	Persch Oral solution 1mg/ml by M/s Barrett Hodgson Pakistan Pvt. Ltd. (Reg. No. 032477)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator XIII	• Applied brand name may be changed.
	Decision: Approved with change of brand name.	
1700.	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	Ronex Syrup 1g/ 5ml
	Composition	Each 5ml contains: Piracetam …….1g
	Diary No. Date of R& I & fee	Dy.No.41083;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Psycho-stimulant /Nootropic
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	120ml& As per SRO
	Approval status of product in Reference Regulatory Authorities	Piracetam Arrow 20% oral solution (Approved in ANSM France)
	Me-too status	Benlon Syrup of M/s Akhai Pharmaceuticals (Reg. # 050796)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator XIII	• No USP or BP monograph is available for the applied formation.
	Decision: Approved with innovator's specifications	
1701.	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	Espasevit Liquid Syrup 4mg/ 5ml

	Composition	Each 5ml contains: Ondansetron as OndansetronHCl ……. 4mg
	Diary No. Date of R& I & fee	Dy.No.41088;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Antacid/ Anti-emetic
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ondanles by Neo Medix Pharma (Reg. # 066472)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications	
1702.	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	Domep 5mg/5ml Liquid suspension
	Composition	Each 5ml suspension contains: Domperidone ……. 5mg
	Diary No. Date of R& I & fee	Dy.No.41109;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Propulsive/ Drugs for GIT disorders
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 90ml & 120ml& As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Domi 1mg/ml oral suspension of M/s Heal Pharma (R# 048021)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications	
1703.	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	R-Tine 10mg/5ml Liquid syrup
	Composition	Each 5ml contains: Memantine hydrochloride …….... 10mg
	Diary No. Date of R& I & fee	Dy.No.41104;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Anti- dementia drug
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	120ml /MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Zexa 10mg/5ml syrup by English Pharma (Reg. No. 071544)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications	
1704.	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	Megatron 50mg/5ml Syrup
	Composition	Each 5ml contains: Iron-III Hydroxide as Polymaltose Complex..... 50mg
	Diary No. Date of R& I & fee	Dy.No.41056;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Anti-anemic
	Type of Form	Form 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml, 120ml, 450ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Irofer Syrup of M/s Hicon Pharmaceuticals(Reg. # 041475)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1705.	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	Rozic 20mg/5ml Syrup
	Composition	Each 5ml contains: Zinc Sulphate monohydrate eq. to Elemental Zinc … 20mg
	Diary No. Date of R& I & fee	Dy.No.41131;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Zinc Supplement
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml &Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Osiris 20mg/5ml of M/s Sami (Reg. # 066902)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	• The international availability of the applied formulation could not be confirmed.
	Decision: 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.	
1706.	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	Zencit 1mg/ml Liquid Syrup
	Composition	Each ml contains: Cetirizine dihydrochloride …… 1mg
	Diary No. Date of R& I & fee	Dy.No.41090;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml & 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Stamin Oral Solution 1mg/ml of M/s ShaiganPharma (Reg. # 027006)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1707.	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	Katif 1mg/ 5ml Liquid Syrup
	Composition	Each 5ml contains: Ketotifen (as hydrogen fumarate) …… 1mg
	Diary No. Date of R& I & fee	Dy.No.41105;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Zaditen 1mg/5ml oral solution by M/s Sigma Tau, ANSM approved
	Me-too status	Tifien Syrup of M/s Hicon Pharma (Reg. # 041474)

	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Deferred for evidence of approval of applied formulation in reference agencies as applied formulation is Ketotifen (as hydrogen fumarate) 1mg/5ml syrup, which is different from quoted reference i.e. ketotifen (as fumarate) 1mg/5ml syrup.	
1708.	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	Rocit 100mg/ml Liquid Syrup
	Composition	Each ml contains: Citicoline (as sodium) …… 100mg
	Diary No. Date of R& I & fee	Dy.No.41134;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Psycho-stimulant / Nootropics
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30ml & 60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Citicoline Kern Pharma 100 mg / ml oral solution EFG by KERN PHARMA, SL (Spain Approved)
	Me-too status	Cercolin syrup of M/s Schazoo Pharma (Reg. No. 048985)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Approved	
	Dry Vial (Steroid) 8 products/ 2 molecules	
1709.	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	Solu- Cort 100mg Injection
	Composition	Each vial contains: Hydrocortisone Sodium succinate eq. to hydrocortisone..100mg
	Diary No. Date of R& I & fee	Dy.No.40170;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Cortef injection of M/s Pharmacia and Upjohn(USFDA Approved)
	Me-too status	Cortizone 100mg Injection of M/s Vision Pharma (R.# 081898)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved with change of brand name	
1710.	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	Solu- Cort 250mg Powder for Injection
	Composition	Each vial contains: Hydrocortisone Sodium succinate eq. to hydrocortisone..250mg
	Diary No. Date of R& I & fee	Dy.No.40203;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Cortef injection of M/s Pharmacia and Upjohn (USFDA Approved)
	Me-too status	Cortizone 250mg Injection of M/s Vision Pharma (R.# 081899)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)

	Remarks of the Evaluator [XIII]	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved with change of brand name	
1711.	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	Solu- Cort 500mg (Powder for) Injection
	Composition	Each vial contains: Hydrocortisone Sodium succinate eq. to hydrocortisone...500mg
	Diary No. Date of R& I & fee	Dy.No.40140;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Cortef injection of M/s Pharmacia and Upjohn (USFDA Approved)
	Me-too status	Cortisone 500mg Injection of M/s Vision Pharma (R.# 081900)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved with change of brand name	
1712.	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	Solu- Cort 1gm Injection
	Composition	Each vial contains: Hydrocortisone Sodium succinate eq. to hydrocortisone... 1g
	Diary No. Date of R& I & fee	Dy.No.40214;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Cortef injection of M/s Pharmacia and Upjohn (USFDA Approved)
	Me-too status	Could not be confirmed in the applied strength (available strengths are 100mg,250mg & 500mg)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	• Firm has Sterile Dry powder Vial (Steroid) Section. • Me- too status could **not** be confirmed in the applied strength as available strengths are 100mg,250mg & 500mg.
	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.	
1713.	Name and address of manufacturer / Applicant	M/s RotexPharma (Pvt.) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Solu- Med 40mg Injection
	Composition	Each vial contains: Methylprednisolone Sodium succinate eq. to methylprednisolone.....40mg
	Diary No. Date of R& I & fee	Dy.No.40239;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu-Medrone 40mg/ml of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Depo-Medrol injection 40mg/ml by M/s Kurram IBD, Pakistan (Reg.#000606)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator [XIII]	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved	

1714.	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	Solu- Med 125mg Injection
	Composition	Each vial contains: Methylprednisolone Sodium succinate eq. to methylprednisolone…… 125mg
	Diary No. Date of R& I & fee	Dy.No.40156;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Medrone 125mg/ml of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Solumedrol injection 125mg of M/s Ali Gohar& Company (Reg. # 000599)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator XIII	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved	
1715.	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	Solu- Med 500mg Injection
	Composition	Each vial contains: Methylprednisolone Sodium succinate eq. to methylprednisolone…… 500mg
	Diary No. Date of R& I & fee	Dy.No.40157;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Medrone 500mg/ml of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Elcort 500mg Injection by M/s Vision Pharma (Reg # 081903)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator XIII	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved	
1716.	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	Solu- Med 1gm Injection
	Composition	Each vial contains: Methylprednisolone Sodium succinate eq. to methylprednisolone…… 1gm
	Diary No. Date of R& I & fee	Dy.No.40221;05-12-2018; Rs.20,000 (05-12-2018)
	Pharmacological Group	Corticosteroid
	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	Solu- Medrone 1g/ml of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Solu- medrol injection 1000mg by M/s Kurram, ISB (Reg. # 005806)
	GMP status	New Section (Inspection Date: 19th Sep. 2018)
	Remarks of the Evaluator XIII	Firm has Sterile Dry powder Vial (Steroid) Section.
	Decision: Approved	

~~Case no. 03 Registration applications for local manufacturing of (veterinary) drugs.~~

a. Deferred Cases

Evaluator PEC XIII

1717.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceuticals, Plot # 2 Street SS-2 RCCI, Industrial Area, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Citrolyte Powder 100g
	Composition	Each 100gm powder contains: Vitamin C……..….20gm Paracetamol……..2gm Magnesium Sulphate.....3.5gm Calcium Carbonate……4.5gm Potassium Chloride…..…4gm
	Diary No. Date of R& I & fee	Dy.No.370;25-05-2011;8000/-(25-05-2011)& Rs.12,000/- (05-12-2014)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30g, 50g, 100g, 250g, 500g, 1kg, 10kg, 25kg & Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Spin-C Powder of M/s Leads Pharmaceuticals, Islamabad (Reg. # 078239)
	GMP status	Last GMP inspection was conducted on 11-05-18 andthe report concludes renewal of DML.
	Previous remarks of the Evaluator	Firm has Oral Powder Section (Veterinary).
	Previous decision	Deferred in 286th DRB meeting for submission of correct pharmacological group.
	Evaluation by PEC	• Firm has submitted its correct pharmacological group as NSAIDs + VITAMIN + ELECTROLYTES.
	Decision: Approved	
1718.	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: Doramectin ……..10mg
	Diary No. Date of R& I & fee	Dy.No.7192;26-02-2018; Rs.20,000 (26-02-2018)
	Pharmacological Group	Anti- parasitic
	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 SelmorePharma (Reg. # 035149)
	GMP status	Last GMP inspection was conducted on 09-05-2016 and the report concludes satisfactory GMP compliance.
	Previous remarks of the Evaluator	• Firm has General Injectable Liquid (Veterinary) section. • **Vial** section needs to be confirmed. • GMP report has some **observations**.
	Previous decision	Deferred in 288th DRB meeting for updated status of GMP of the firm form QA & LT division and confirmation of injectable vial section.
	Evaluation by PEC	• The firm has submitted its latest inspection report

		dated: 10-10-2018 and the report concludes renewal of DML. • General Liquid Injectable (vial) section is confirmed by the submitted GMP report. • No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications	
1719.	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: Doramectin ……..10mg
	Diary No. Date of R& I & fee	Dy.No.7193;26-02-2018; Rs.20,000 (26-02-2018)
	Pharmacological Group	Anti- parasitic
	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.
	Previous remarks of the Evaluator	• Firm has General Injectable Liquid (Veterinary) section. • **Vial** section needs to be confirmed. • GMP report has some **observations**.
	Previous decision	Deferred in 288th DRB meeting for updated status of GMP of the firm form QA & LT division and confirmation of injectable vial section.
	Evaluation by PEC	• The firm has submitted its latest inspection report dated: 10-10-2018 and the report concludes renewal of DML. • General Liquid Injectable (vial) section is confirmed by the submitted GMP report. • No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications	
1720.	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: 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
	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.
	Previous remarks of the Evaluator	Firm has General Injectable Liquid (Veterinary) section. • **Vial** section needs to be confirmed.

		• GMP report has some **observations**.
	Previous decision	Deferred in 288th DRB meeting for updated status of GMP of the firm form QA & LT division and confirmation of injectable vial section.
	Evaluation by PEC	• The firm has submitted its latest inspection report dated: 10-10-2018 and the report concludes renewal of DML. • General Liquid Injectable (vial) section is confirmed by the submitted GMP report. • No USP or BP monograph is available for the applied formulation.
	Decision: Approved with innovator's specifications	

Case No.04: Registration applications of Categories to be considered on Priority.

a. Export facilitation

1721.	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: 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 in MHRA
	Me-too status	Vinjec -1000mg Injection of M/s Bosch Pharma (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.
	Decision: Approved	
1722.	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: 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	Ticard Tablet 90mg of M/s Atco (Reg. # 089364)
	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. • Tablet General Section is available in the firm as mentioned in the submitted section approval letter. • Initially, film- coating was not applied in the master formulation. Now, the firm has revised its

		formulation as film-coated tablet. • Stability is required against the applied formulation according to the decision of 278th meeting.
	Decision: Deferred for submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version.	
1723.	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: 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. • No USP or BP monograph is applied for the applied formulation. • Film- coating was not applied in the master formulation. Then, the firm revised its formulation accordingly with submission of Rs. 5000/- fees.
	Decision: Approved with innovator's specifications	
1724.	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: 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**
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Revoladetablet 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. • No USP or BP monograph is applied for the applied formulation.
	Decision: Approved with innovator's specifications	
1725.	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: 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	**Not claimed**
	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.
	Remarks of the Evaluator [XIII]	• Tablet General Section is available in the firm as mentioned in the submitted section approval letter. • No USP or BP monograph is applied for the applied formulation.
	Decision: Approved with innovator's specifications	

Evaluator PEC-XIV

Case no. 01 Registration applications for local manufacturing of (Human) drugs

Deferred cases:

1726.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals (pvt) Ltd, 14 Km Adyala Road, Post office Dhgal, Rawalpindi-Pakistan
	Brand Name +Dosage Form + Strength	Clycin T Gel
	Composition	Each gram of Topical gel contains: Clindamycin (as phosphate)……10mg
	Diary No. Date of R& I & fee	Dy. No.2978; 30-06-2016; Rs.20,000/- (29-06-2016)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's x 5gm; Rs. 75; 1's x 10gm; Rs. 130
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Uniclin Gel by M/s Kaizen Pharma, Karachi (R. No. 076304)
	GMP status	Inspection report dated 17-08-2016 recommended for the grant of additional sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for submission of latest GMP inspection report conducted within last 1 year by DRAP. **(M-274)**
	Evaluation by PEC	Copy of panel inspection dated 06-08-2018 concluded that the company is found complying GMP as of today and panel unanimously agreed to issue GMP certificate.
	Decision: Approved.	
1727.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Post office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Zegrid 40 mg capsule
	Composition	Each capsule contains:- 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 Specification	USP
	Pack size & Demanded Price	14's/ As per SRO
	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
	Previous remarks of the Evaluator.	• 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. • Stability data of pellets for 3 batches was provided
	Previous decision(s)	Deferred for submission of differential fee in case of import of pellets **(M-288).**
	Evaluation by PEC	• The firm has submitted differential fee of Rs. 80,000/- (Deposit slip # 1902995) dated 08-05-2019.
	Decision: Approved.	
1728.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals, Pvt Ltd, 14 km Adyala Road, Post office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Zegrid 20 mg capsule
	Composition	Each capsule contains:- Omeprazole enteric coated pellets eq. to omeprazole……20mg
	Diary No. Date of R& I & fee	Dy. No.623; 06-01-2017; Rs. 20,000/-
	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.	Losec 20 mg hard gastro-resistant capsules 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
	Previous remarks of the Evaluator.	• 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. • Stability data of pellets for 3 batches was provided
	Previous decision(s)	Deferred for submission of differential fee in case of import of pellets **(M-288).**
	Evaluation by PEC	• The firm has submitted differential fee of Rs. 80,000/- (Deposit slip # 1902994) dated 08-05-2019.
	Decision: Approved.	
1729.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, Plot No. 168, Sector No.23, Korangi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Listan AH tablet
	Composition	Each film coated tablet contains: Amlodipine besylate eq to Amlodipine…..10mg Valsartan……..…160mg Hydrochlorothiazide……..25mg
	Diary No. Date of R& I & fee	Dy. No. 175, 27-01-2017, Rs.20,000/- (24-01-2017)
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT by Novartis Pharma (**USFDA approved**)
	Me-too status	Exforge HCT 10/160/25MG by Novartis Pharma
	GMP status	The inspection report conducted on 23-11-2016 concluded that the firm is employing resources for upgradation as per approved layout plan.

	Previous remarks of the Evaluator.	Last inspection report is older than 1 year.
	Previous decision(s)	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. **(M-279)**
	Evaluation by PEC	Copy of inspection dated 24-07-2018 concluded as follows: "During inspection active production was seen under way in Tablet (G), Capsule (G) and in veterinary sections. Up-gradation is expected to be completed within next few months. After that firm would be able for inspection of grant of renewal of their DML and & regularization of LoP. The firm was further advised to get the changes made into approved LoP, reapproved from concerned division. Based on the above stated observations, their current GMP compliance level is rated as GOOD."
	Decision: Approved.	
1730.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, Plot No. 168, Sector No.23, Korangi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Listan AH tablet
	Composition	Each film coated tablet contains: Amlodipine besylate eq to Amlodipine…..5mg Valsartan……160mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy. No. 171, 27-01-2017, Rs.20,000/- (24-01-2017)
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT by Novartis Pharma (USFDA)
	Me-too status	Exforge HCT 5/160/25MG by Novartis Pharma
	GMP status	The inspection report conducted on 23-11-2016 concluded that the firm is employing resources for upgradation as per approved layout plan.
	Previous remarks of the Evaluator.	Last inspection report is older than 1 year.
	Previous decision(s)	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. **(M-279)**
	Evaluation by PEC	As recoded for above application
	Decision: Approved.	
1731.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, Plot No. 168, Sector No.23, Korangi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Listan AH tablet
	Composition	Each film coated tablet contains: Amlodipine besylate eq to Amlodipine…..10mg Valsartan……320mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy. No. 174, 27-01-2017, Rs.20,000/- (24-01-2017)
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT by Novartis Pharma (USFDA)
	Me-too status	Exforge 10/320/25MG by Novartis Pharma
	GMP status	The inspection report conducted on 23-11-2016 concluded that the firm is employing resources for upgradation as per approved layout plan.

	Previous remarks of the Evaluator.	Last inspection report is older than 1 year.
	Previous decision(s)	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. **(M-279)**
	Evaluation by PEC	As recoded for above application
	Decision: Approved.	
1732.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, Plot No. 168, Sector No.23, Korangi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Listan AH tablet
	Composition	Each film coated tablet contains: Amlodipine besylate eq to Amlodipine…..5mg Valsartan……160mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy. No. 173, 27-01-2017, Rs.20,000/- (24-01-2017)
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT by Novartis Pharma (USFDA)
	Me-too status	Exforge HCT 5/160/12.5MG by Novartis Pharma
	GMP status	The inspection report conducted on 23-11-2016 concluded that the firm is employing resources for upgradation as per approved layout plan.
	Previous remarks of the Evaluator.	Last inspection report is older than 1 year.
	Previous decision(s)	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. **(M-279)**
	Evaluation by PEC	As recoded for above application
	Decision: Approved.	
1733.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, Plot No. 168, Sector No.23, Korangi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Listan AH tablet
	Composition	Each film coated tablet contains: Amlodipine besylate eq to Amlodipine…..10mg Valsartan……160mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy. No. 172, 27-01-2017, Rs.20,000/- (24-01-2017)
	Pharmacological Group	Antihypertensive
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	14's, 28's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT by Novartis Pharma (USFDA)
	Me-too status	Exforge HCT 10/160/12.5MG by Novartis Pharma
	GMP status	The inspection report conducted on 23-11-2016 concluded that the firm is employing resources for upgradation as per approved layout plan.
	Previous remarks of the Evaluator.	Last inspection report is older than 1 year.
	Previous decision(s)	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. **(M-279)**
	Evaluation by PEC	As recoded for above application
	Decision: Approved.	

1734.	Name and address of manufacturer / Applicant	M/s Amarant Pharmaceuticals (Pvt) Ltd, Plot No. 168, Sector No.23, Korangi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Cefirant 200mg Capsule
	Composition	Each capsule contains: Cefixime as trihydrate ……200 mg
	Diary No. Date of R& I & fee	Dy.No.481, 12-02-2011, Rs.8000/-, Rs.12,000/-, 25-6-2014
	Pharmacological Group	3rd Generation cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	6's ; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in Spain
	Me-too status	Soxime Capsule 200mg by Swat Pharmaceuticals.
	GMP status	The inspection report conducted on 23-11-2016 concluded that the firm is employing resources for upgradation as per approved layout plan.
	Previous remarks of the Evaluator.	Last inspection report is older than 1 year.
	Previous decision(s)	Deferred as per decision of 250th meeting of Registration Board and verification of fee challan of Rs. 8000/- (**M-268)** 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. **(M-279)**
	Evaluation by PEC	As recoded for above application
	Decision: Approved.	
1735.	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	ROTANA 60mg/1.5ml Injection
	Composition	Each Injection Vial Contains: Cabazitaxel (anhydrous)…….60mg, Polysorbate 80 q.s……1.5ml Each Diluent Vial Contains: Ethanol 13% (w/w) in Water for injection…….4.5ml
	Diary No. Date of R& I & fee	Diary No:8329, 11-07-2017, Rs: 20,000/-
	Pharmacological Group	Antineoplastic agent (Taxane)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Combine Pack of 1 Vial x 1.5ml of injection & 1 Vial x 5.7ml Diluent/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	CABAZITAXEL SANOFI cabazitaxel 60mg/1.5mL concentrated injection vial by Sanofi-Aventis Australia Pty Ltd (TGA Approved)
	Me-too status	Jevtana Injection 60mg/1.5ml by Sanofi-aventis (Reg#078125)
	GMP status	30-03-2017. Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for deliberation on manufacturing of diluent **(M-275)**. Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-285)**. Deferred for deliberation upon regulatory requirements for registration of diluent alongwith applied formulation **(M-287)**.
	Evaluation by PEC	The firm has referred the decision of 274th meeting wherein Registration decided as under: "For diluents in combo pack with drug, same fee as for product and diluents shall be considered and single registration number shall be allotted to combo pack." • The firm is granted GMP certificate based on inspection

		conducted on 17-03-2017. • The firm has submitted that DRAP has already approved and issued us registration letter in Combo pack for Inj. Doxetal 120mg/6ml having 6ml vial injection plus 9ml diluent.
	Decision: Approved with innovator's specifications.	
1736.	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	ROTAFER 15mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Calcium Folinate eq. to folinic acid…15mg
	Diary No. Date of R& I & fee	Diary No:8684, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Detoxifying agent for antineoplastic treatment
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5's x 2ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL LEUCOVORIN CALCIUM Folinic Acid 15mg/2mL (as calcium folinate) Injection by Hospira Australia Pty Ltd (TGA Approved)
	Me-too status	Kunyrin 15mg/2ml injection by Al-Habib (Reg. No. 021042)
	GMP status	30-03-2017; Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer **(M-275)**.
	Evaluation by PEC	• The firm has submitted that since it is not a cytotoxic anticancer product, therefore kindly grant the registration for Rotafer 15mg /2ml in General Liquid Ampoule section.
	Decision: Approved with innovator's specifications.	
1737.	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	ROTAFER 50mg/5ml Injection
	Composition	Each 5ml Ampoule Contains: Calcium Folinate eq. to folinic acid…50mg
	Diary No. Date of R& I & fee	Diary No:8683, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Detoxifying agent for antineoplastic treatment
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5's x 5ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	DBL LEUCOVORIN CALCIUM Folinic Acid 50mg/5mL (as calcium folinate) Injection by Hospira Australia Pty Ltd (TGA Approved)
	Me-too status	Kunyrin 50mg/5ml injection by Al-Habib (Reg. No. 021041)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer **(M-275)**.
	Evaluation by PEC	• The firm has submitted that since it is not a cytotoxic anticancer product, therefore kindly grant the registration for Rotafer 50mg /2ml in General Liquid Ampoule section.
	Decision: Approved with innovator's specifications.	

1738.	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	ONCOFU 250mg/5ml Injection
	Composition	Each 5ml Ampoule Contains: Fluorouracil…250mg
	Diary No. Date of R& I & fee	Diary No:8687, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Antimetabolite (Pyrimidine analogue)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Pack of 1 Amp x 5ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fluorouracil Injection, 50 mg/ml, solution for injection by medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6 22880 Wedel Germany (MHRA Approved)
	Me-too status	Fivuflu 250mg injection by Atco (Reg.# 045756)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	• Confirmed as vial in MHRA but firm has applied in ampoule packaging. • Evidence of vial from available me-too database
	Previous decision(s)	Deferred for clarification/justification on scientific basis for applied packaging material as reference product approved by MHRA of UK is available in glass vial whereas firm has applied for glass ampoule.**(M-275).** Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-285).** Deferred for evidence of me-too status in applied fill volume of 5 ml **(M-287)**.
	Evaluation by PEC	The firm has referred the decision of 274th meeting wherein Registration Board has decided as me-too is available in 10ml vial with type-1 glass and, the container closure is more safe as ampoule does not have rubber stopper and thus DRB approved that product. The firm is granted GMP certificate based on inspection conducted on 17-03-2017 The firm has submitted me-too reference "UTORAL injection of Al-Habib Corporation (Reg#021046)" which has been verified from available database.
	Decision: Approved.	
1739.	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	ASP 10,000IU Powder for Injection
	Composition	Each Vail Contains: L-Asparaginase……..10,000IU
	Diary No. Date of R& I & fee	Diary No:8173, 10/07/2017 , Rs: 20,000/-
	Pharmacological Group	Protein Synthesis inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1's Vial/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Leunase 10,000KU injection vial by Sanofi-Aventis Australia Pty Ltd (TGA Approved)
	Me-too status	Leunase 10,000KU injection by M/s S. Ejazuddin and Co. (Reg no. 044896)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections

	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Dry Powder Vial (Oncology) section in the light of decision of Registration Board in its 271st meeting regarding "Specific manufacturing requirements for certain classes of drugs" **(M-275)**. Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-285)**. Deferred for clarification of origin of API whether biological source or synthetic **(M-287)**.
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted source of API as "Synthetic".
	Decision: Registration Board deferred the case for further delibration regarding source of API.	
1740.	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	OCTERO 0.05mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Octreotide (as acetate)……0.05mg
	Diary No. Date of R& I & fee	Diary No:8686, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Somatostatin analogue (Cytostatics)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack of 5 Amp x 1ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANDOSTATIN (octreotide acetate)50mcg injection, solution by M/s Novartis Pharmaceuticals Corporation **(USFDA Approved)**
	Me-too status	Sandostatin 0.05mg injection by Novartis (Reg. No. 013473)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer. Moreover, source of Octreotide (synthetic or biological) shall be submitted by the applicant along with relevant documents **(M-275)**. Deferred for clarification of origin of API whether biological source or synthetic **(M-287)**.
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted source of API as "Synthetic".
	Decision: Registration Board deferred the case for further delibration regarding source of API.	
1741.	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	OCTERO 0.1mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Octreotide (as acetate)……0.1mg
	Diary No. Date of R& I & fee	Diary No:8685, 13/07/2017 , Rs: 20,000/-
	Pharmacological Group	Somatostatin analogue (Cytostatics)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Pack of 5 Amp x 1ml, MRP. Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	SANDOSTATIN (octreotide acetate)100mcg injection, solution by M/s Novartis Pharmaceuticals Corporation (USFDA Approved)

	Me-too status	Sandostatin 0.1mg injection by Novartis (Reg. No. 013472)
	GMP status	30-03-2017 Grant of Additional Sections Panel recommends grant of Additional Sections
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation/justification for manufacturing of the applied product in Liquid Ampoule (Oncology) section as applied product is not cytotoxic anti-cancer. Moreover, source of Octreotide (synthetic or biological) shall be submitted by the applicant along with relevant documents **(M-275)**. Deferred for clarification of origin of API whether biological source or synthetic **(M-287)**.
	Evaluation by PEC	The firm is granted GMP certificate based on inspection conducted on 17-03-2017. The firm has submitted source of API as "Synthetic".
	Decision: Registration Board deferred the case for further delibration regarding source of API.	
1742.	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	CITROMED oral Sachet
	Composition	Each 5gm sachet contains: Sodium Bicarbonate……1.76g Sodium citrate……...0.63g Citric acid……0.72g Tartaric acid……..0.89g
	Diary No. Date of R& I & fee	40241, 05-12-2018, 20,000/-, 04-12-2018
	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.	TGA Approved formulation (4g) is Sodium bicarbonate…..1.76gm Sodium citrate……..0.63gm Citric acid……0.72gm Tartaric acid……..0.89gm
	Me-too status	Citro soda Sachet of Abbott Labs Sodium Bicarbonate……1.76g Sodium citrate……...0.63g Citric acid……0.72g Tartaric acid……..0.98g Me-too is different.
	GMP status	Panel inspection dated 19-09-2018 recommended the grant of additional section (Sachet General).
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following: **(M-288)** • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	The firm has submitted revised Form-5 with fee challan of Rs. 5,000/-, (Deposit slip # 1930973) dated 30-04-2019. Revised composition is below: Each 5gm sachet contains: Sodium Bicarbonate……2.145g Sodium citrate……...0.765g Citric acid……0.88g

		Tartaric acid……..1.075g The firm has submitted me-too reference of Citrosoda sachet by Abbott (5g) (Reg # 008749) Sodium bicarbonate…..2.145gm Sodium citrate…….0.765gm Citric acid……..…0.88gm Tartaric acid……..1.075gm
	Decision: Deferred for submission of differential fee for revision of formulation.	
1743.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Brethease 100mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide……..100mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	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.	Not confirmed
	Me-too status	Combivair 100mcg + 6mcg capsule of M/s Highnoon
	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 guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID with following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form.
	Evaluation by PEC	The firm has submitted copy of product specific inspection conducted by Director DTL, Karachi and Area FID which concludes as below: "*In the light of manufacturing, Quality Control, Storage facilities and technical persons met, the panel is of the view to recommend Registration of a) Aclidum Capsule, b) Brethease 200mcg/6mcg Capsule, c) Brethease 100mcg/6mcg Capsule, d) Brethease 400mcg/6mcg Capsule to the firm under the Drug Act, 1976."*
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.	
1744.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Brethease 200mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate…….6mcg Budesonide……200mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in	Not confirmed

	Reference Regulatory Authorities.	
	Me-too status	Combivair 200mcg + 6mcg capsule of M/s Highnoon
	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 guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID alongwith following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form.
	Evaluation by PEC	As recoded for above application
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.	
1745.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone , Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Brethease 400mcg/6mcg Capsule
	Composition	Each capsule contains: Formoterol Fumarate……6mcg Budesonide……400mcg
	Diary No. Date of R& I & fee	Dy.No. 939, 28-10-2013, 20,000/-, 28-10-2013
	Pharmacological Group	Corticosteroid + selective $beta_2$–adrenergic agonist
	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.	Not confirmed
	Me-too status	Combivair 400mcg + 6mcg capsule of M/s Highnoon
	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 guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection by Director DTL Karachi alongwith FID alongwith following verifications **(M-243)**: • Confirmation of approval of formulation by the stringent regulatory agencies. • Confirmation of API in ultramicronized form.
	Evaluation by PEC	As recoded for above application
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.	
1746.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Limited, Located at plot No. E-145 to E-149, North Western Industrial Zone , Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Aclidum Capsule
	Composition	Each capsule contains: Aclidinum Bromide 400mcg eq. to Aclidinum …343mcg
	Diary No. Date of R& I & fee	Dy.No. 188, 04-03-2014, 20,000/-, 04-03-2014
	Pharmacological Group	Anticholinergic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 2250/ pack of 15's (Rs. 150/ capsule)
	Approval status of product in Reference Regulatory Authorities.	Not confirmed

	Me-too status	Not confirmed
	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 guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for product specific inspection & International availability status in capsule dosage form **(M-243)**:
	Evaluation by PEC	As recoded for above application
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.	
1747.	Name and address of manufacturer / Applicant	M/s. Jaens Pharmaceutical Industries (Pvt) Ltd. Lahore Contract manufactured by M/s. English Pharma, Lahore
	Brand Name +Dosage Form + Strength	Tenum 1gm Injection (IV)
	Composition	Each vial contains: Meropenem trihydrate equivalent to meropenem…1g
	Diary No. Date of R& I & fee	Dy No. 3087, 15-05-2013, Rs.50000/-, 15-05-2013
	Pharmacological Group	Carbapenems (ATC code: J01DH02)
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's; As per SROs
	Approval status of product in Reference Regulatory Authorities.	Meronem IV 1g by Pfizer Limited (MHRA Approved)
	Me-too status	Merem 1g injection by Global Pharma
	GMP status	GMP inspection of M/s Jeans pharma dated 20-12-2017 concluded that M/s Jeans Pharmaceuticals 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. CLB in its 265th meeting held on 9th & 10th August, 2018 has considered and approved the grant of DML (no. 000886) by way of formulation to M/s Nicholas pharmaceuticals, Islamabad.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of section approval for non-penicillin B-Lactam antibiotics & clarification of Pharmacological group **(M-267)**.
	Evaluation by PEC	The firm M/s Jeans Pharma has requested to change the contract manufacturing from M/s English Pharma to M/s Nicholas Pharmaceuticals, Plot#34, Street#SS-2, National Industrial Zone, Islamabad. M/s Nicholas Pharmaceuticals, Islamabad has provided Dry Powder Injectable section (Carbapenems) section. The firm has clarified the pharmacological group "Carbapenems".
	Decision: Registration Board acceded to the firm's request and approved the formulation for contract manufacturing with M/s Nicholas Pharmaceuticals, Plot#34, Street#SS-2, National Industrial Zone, Islamabad.	
1748.	Name and address of manufacturer / Applicant	M/s. Jaens Pharmaceutical Industries (Pvt) Ltd. Lahore Contract manufactured by M/s. English Pharma, Lahore
	Brand Name +Dosage Form + Strength	Tenum 500mg Injection (IV)
	Composition	Each vial contains: Meropenem trihydrate equivalent to meropenem…500mg
	Diary No. Date of R& I & fee	Dy No. 3089, 15-05-2013, Rs.50000/-, 15-05-2013
	Pharmacological Group	Carbapenems (ATC code: J01DH02)
	Type of Form	Form-5
	Finished product Specification	USP specifications

	Pack size & Demanded Price	1's; As per SROs
	Approval status of product in Reference Regulatory Authorities.	Meronem IV 500 mg by Pfizer Limited (MHRA Approved)
	Me-too status	Merem 500mg injection by Global Pharma
	GMP status	GMP inspection of M/s Jeans pharma dated 20-12-2017 concluded that M/s Jeans Pharmaceuticals 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. CLB in its 265th meeting held on 9th & 10th August, 2018 has considered and approved the grant of DML (no. 000886) by way of formulation to M/s Nicholas pharmaceuticals, Islamabad.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of section approval for non-penicillin B-Lactam antibiotics & clarification of Pharmacological group **(M-267)**.
	Evaluation by PEC	The firm M/s Jeans Pharma has requested to change the contract manufacturing from M/s English Pharma to M/s Nicholas Pharmaceuticals, Plot#34, Street#SS-2, National Industrial Zone, Islamabad. M/s Nicholas Pharmaceuticals, Islamabad has provided Dry Powder Injectable section (Carbapenems) section. The firm has clarified the pharmacological group "Carbapenems".
	Decision: Registration Board acceded to the firm's request and approved the formulation for contract manufacturing with M/s Nicholas Pharmaceuticals, Plot#34, Street#SS-2, National Industrial Zone, Islamabad.	
1749.	Name and address of manufacturer / Applicant	M/s Paramount Pharamceuticals, Plot No. 36, Industrial triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Omeprazen 40mg
	Composition	Each capsule contains; Omeprazole (as enteric coated pellets 8.5%)…….40mg
	Diary No. Date of R& I & fee	Dy No. 1977: 24-5-2016PKR 20,000/-: 24-5-2016
	Pharmacological Group	Proton pump inhibitor
	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.	Omeprazole by Actavis (USFDA Approved)
	Me-too status	Xempra 40mg Capsule by Genome Pharmaceutical
	GMP status	Last inspection conducted on 30-12-2015
	Previous remarks of the Evaluator.	• GMP inspection is older than 1 year • Source, COA, stability study data and GMP of manufacturer of pellets is not provided
	Previous decision(s)	Deferred for following submissions: **(M-274)** • Source of pellets • Certificate of analysis of pellets • Real time and accelerate stability study data of 3 batches of pellets conducted as per the requirements of zone IV-A • GMP of manufacturer of pellets • Differential fee (if pellets are imported) • GMP inspection report conducted within a period of last 1 year
	Evaluation by PEC	The firm has submitted Followings:

		Source of pellets: M/s Vision pharma The firm is granted GMP certificate based on inspection dated 20-11-2018.
	Decision: Approved.	
1750.	Name and address of manufacturer / Applicant	M/s Macter International (Private) Ltd, F-216, SITE, Karachi.
	Brand Name +Dosage Form + Strength	Ramol Plus Tablet
	Composition	Each film coated tablet contains:- Tramadol HCl……...37.5mg Paracetamol…….325mg
	Diary No. Date of R& I & fee	Diary No.38, 02-08-2011, Rs.8,000.
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 40's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Tramacet tablet of (MHRA approved)
	Me-too status	Radol-P tablet of M/s Regal Pharma
	GMP status	Last GMP inspection conducted on 23/05/2018, the firm is found to be complying at a good level of GMP compliance at the time of inspection.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for the submission of following **(M-256)**:- • Differential fee not attached. • Calculations as base not provided. • Complete description required to be submitted in reference to innovator. • Demanded price of the firm is not as per formulation. • Dosage and indications are not as per the innovator. • Manufacturing method is not complete. • Commitment as per the decision of RB not provided. • Composition is not as per the innovator. • Documents are not signed by the technical staff. • Finished product specifications are not provided. • Fresh Inspection report not attached • Details of HVAC & water treatment system not attached. Registration Board deferred the case for consideration on its turn. **(M-285)**
	Evaluation by PEC	The firm has submitted differential fee of Rs. 12000/-, (Deposit slip#0760287) dated 09-08-2018. Demanded price of the firm is "As per PRC". Commitments as per 251st meeting have been submitted. Documents are signed by the technical staff. The firm has claimed the priority consideration in lieu of Export facilitation. The details of priority molecules were provided by Reg-I vide letter No.F.7-7/2017-Reg-II (Vol-II).
	Decision: Approved.	
1751.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	G-Pas Powder Sachet
	Composition	Dy. No.5997; 13-06-2017; Rs.20,000/- (13-06-2017)
	Diary No. Date of R& I & fee	Each sachet contains: Mebeverine HCl….135mg Ispaghula Husk……..3.5gm
	Pharmacological Group	Laxative and antispasmodic
	Type of Form	Form-5

	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's; As per SRO 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fybogel (MHRA)
	Me-too status	Husk-M by M/s. Genix
	GMP status	Last inspection report 20-1-2017 Panel recommended the grant of additional section.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for clarification as Reference Regulatory Authority product is present as granules for oral suspension **(M-274)**.
	Evaluation by PEC	The firm has submitted that there may be typographic error in the drafting of product in the agenda of 274th meeting i.e., Ispaghula powder instead of ispaghula Husk. The firm has submitted revised Form-5 with fee Challan of Rs.5,000/- (Deposit slip#0748681) dated 29-08-2018.
	Decision: Approved with innovator's specifications.	
1752.	Name and address of manufacturer / Applicant	M/s Venus Pharma, 23-km Multan road, Lahore
	Brand Name +Dosage Form + Strength	CLARITHROVIN Tablets
	Composition	Each Film coated tablet contain: Clarithromycin……..…..500mg
	Diary No. Date of R& I & fee	04.06.2010, Rs. 8,000/-, 05.11.2013, Rs. 12,000/- (Photocopy attached)
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 398/10's
	Approval status of product in Reference Regulatory Authorities.	BIAXIN of M/s Abbvie approved by USFDA
	Me-too status	Klarinor 500 mg Tablets by M/s Nortech Pharmaceuticals (Pvt) Ltd (Reg#077970)
	GMP status	The panel of inspectors dated 09-07-2018 recommends for grant of GMP certificate for export purpose only.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for the submission of following: **(M-261)** i. Inspection report ii. Commitment as per decision of board iii. Finished product specification are incomplete. iv. Fee of Rs. 8000/- and 12000/- is Photocopy
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with fee challan of Rs. 5,000/- (Deposit slip#1934401) dated 26-04-2019.
	Decision: Approved.	
1753.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt. Ltd., Plot No. E-178, SITE Super Highway Phase II, Karachi.
	Brand Name +Dosage Form + Strength	Cyclomax-B 20mg Capsule
	Composition	Each capsule contains: Piroxicam-Beta-Cyclodextrin…….20mg
	Diary No. Date of R& I & fee	Dy.1339, 28-11-2016, Rs.20,000/-
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	FELDENE 20mg CAPSULES by Pfizer Limited. (MHRA approved)

	Me-too status	FELDEN 20MG CAP by Pfizer Karachi. (Reg#006349)
	GMP status	Last inspection report dated 11-06-2018 confirms satisfactory compliance to GMP.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred as reference product contains piroxicam base only **(M-264)**.
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with correct salt form as below: Each capsule contains: Piroxicam…….20mg Fee challan of Rs.5,000/- (Deposit slip # 0848058) dated 04-02-2019 has been submitted.
	Decision: Registration Board approved with innovator's specifications and revised formulation as below: **Each capsule contains:** **Piroxicam…….20mg**	
1754.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt. Ltd., Plot No. E-178, SITE Super Highway Phase II, Karachi.
	Brand Name +Dosage Form + Strength	Dimed-S Lotion 0.05% + 3%
	Composition	Each ml contains: Betamethasone dipropionate……0.05% Salicylic Acid…….3%
	Diary No. Date of R& I & fee	Dy. No. 1192, 24-11-2016, Rs.20,000/-
	Pharmacological Group	Anti-inflammatory / Antipruritic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC As per PRC
	Approval status of product in Reference Regulatory Authorities.	Diprosalic lotion by Schering-Plough (Canada)
	Me-too status	Betasalic by Atco
	GMP status	Last inspection report dated 11-06-2018 confirms satisfactory compliance to GMP.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred as reference product contains piroxicam base only **(M-264)**.
	Evaluation by PEC	The firm has revised the strength of formulation as below: Each ml contains: Betamethasone Dipropionate……0.05% Salicylic Acid…….2% **International availability:** 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) Fee challan of Rs.5,000/- (Deposit slip # 0848059) dated 04-02-2019 and Rs.15,000/- (Deposit Slip # 1936828) dated 13-05-2019.
	Decision: Registration Board approved with innovator's specifications and revised formulation as below: **Each ml contains:** **Betamethasone Dipropionate……0.05%** **Salicylic Acid…….2%**	
1755.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals (Pvt.) Ltd, Plot # 16/I-phase IV, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Clarinom 250mg Dry Suspension
	Composition	Each 5ml contains:- Clarithromycin (as granules)…….250mg

	Diary No. Date of R& I & fee	Dy No. 667, 16-7-2012, Rs.8000/-, Rs.12,000/-, 26-11-2014
	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.	Clarithromycin 250 mg/5ml suspension (MHRA approved)
	Me-too status	Malacin DS 250mg by M/s Bosh Pakistan
	GMP status	GMP inspection conducted on 12-05-2018 showed good level of compliance.
	Previous remarks of the Evaluator.	Source of Granules: M/s Surge Pharma
	Previous decision(s)	Deferred for clarification of Dissolution test of Clarithromycin taste masked coated granules in acidic medium i.e 0.1N HCl as FDA dissolution database recommends dissolution of Clarithromycin suspension in phosphate buffer only **(M-265)**.
	Evaluation by PEC	The firm has submitted that "Clarithromycin for oral suspension is mentioned in official monograph of USP, and USP has not described the dissolution test for Clarithromycin Dry suspension. The dissolution test of clarithromycin granule is in-house test according to USFDA dissolution database. Updated specifications, analytical method and USP monograph has been attached."
	Decision: Approved.	
1756.	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	Hi-Mine 4mg Tablet
	Composition	Each Film coated Tablet Contains: Galantamine as Hydrobromide……4mg
	Diary No. Date of R& I & fee	26803, 29-12-2107, 20,000/-, 22-12-2017
	Pharmacological Group	Anticholinesterase
	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.	USFDA approved
	Me-too status	Reminyl 4mg Tablet by Janssen-Cilag Pharma
	GMP status	Last GMP inspection conducted on 18-01-2018, and the report concludes that keeping in view of overall GMP compliance, the panel recommends the Renewal of DML.
	Previous remarks of the Evaluator.	• Reference product is uncoated tablet while applied formulation is film coated tablet. Clarification /Revision of Form-5 is required.
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-278)**.
	Evaluation by PEC	The approval status of applied formulation with film coating has been confirmed in MHRA "Reminyl 4mg Film coated tablet."
	Decision: Approved.	
1757.	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: 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.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	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" **(M-288)**.
	Evaluation by PEC	The firm has submitted that the applied product is Non-steroidal Antiestrogen. 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.
	Decision: 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.	
1758.	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: Tamoxifen citrate equivalent to Tamoxifen……20mg
	Diary No. Date of R& I & fee	30424, 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 20mg Tablet by Novartis Pharma (Reg no.047671)
	GMP status	The firm was granted GMP certificate based on inspection conducted on 22-02-2018.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	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" **(M-288)**.
	Evaluation by PEC	The firm has submitted that the applied product is Non-steroidal Antiestrogen. 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.
	Decision: 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.	

1759.	Name and address of manufacturer / Applicant	M/s Getz Pharma (Pvt) Limited, 29-30-Sector 27, Korangi, Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	TREVIAMET XR Tablets
	Composition	Each extended release tablet contains: Sitagliptin as Phosphate monohydrate……100mg Metformin Hydrochloride……1000mg
	Diary No. Date of R& I & fee	Dy. No 1803 dated 14-12-2012, 50,000 dated 12-12-2012
	Pharmacological Group	DPP-4 & Biguanide
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	Rs. 169 /- per tablet/ Pack of 14's & 30's
	Approval status of product in Reference Regulatory Authorities.	Janumet XR (USFDA approved)
	Me-too status	Tagipmet XR 100/1000mg by M/s Highnoon
	GMP status	The firm was granted GMP certificate based on inspection dated 16-02-2018.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for submission of laboratory scale scientifically rational stability data as per requirements decided in the 251st meeting of Registration Board **(M-257)**.
	Evaluation by PEC	The firm has submitted that the subject product is the line extension of our already registered and marketed products "Treviamet XR Tablets 50mg + 500mg (Reg#085938) and "Treviamet XR Tablets 50mg + 1000mg (Reg#085939)". Treviamet XR Tablets 100mg + 1000mg is dose proportional to our other registered strengths as well as the qualitative composition, manufacturing process and testing procedure is same as that of Treviamet XR Tablets 50mg + 500mg & 50mg + 1000mg.
	Decision: Deferred for submission of stability data as per requirements decided in the 278th meeting of Registration Board.	
1760.	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	Epirom Injection 500mg
	Composition	Each vial contains: Cefpirome Sulphate (with sodium carbonate)…….500mg
	Diary No. Date of R& I & fee	Dy. No.14237; 07-09-2017; Rs. 20,000/-
	Pharmacological Group	Cephalosporin (Antibiotics)
	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 in ANSM
	Me-too status	Pirome Injection 500mg of Cirin Pharmaceuticals
	GMP status	New License (Inspection Date: 07th June 2017)
	Previous remarks of the Evaluator.	The applied formulation is repealed in ANSM and it is not found in other reference agencies.
	Previous decision(s)	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 approval status of applied formulation has been confirmed in ANSM.
	Decision: Approved with innovator's specifications.	
1761.	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	Epirom Injection 1gm

	Composition	Each vial contains: Cefpirome Sulphate (with sodium carbonate).....1gm
	Diary No. Date of R& I & fee	DyNo.14232; 07-09-2017; Rs. 20,000/-
	Pharmacological Group	Cephalosporin (Antibiotics)
	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 in ANSM
	Me-too status	Pirome Injection 1gm of Cirin Pharmaceuticals
	GMP status	New License (Inspection Date: 07th June 2017)
	Previous remarks of the Evaluator.	The applied formulation is repealed in ANSM and it is not found in other reference agencies.
	Previous decision(s)	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 approval status of applied formulation has been confirmed in ANSM.
	Decision: Approved with innovator's specifications.	
1762.	Name and address of manufacturer / Applicant	M/s. Remedy Pharmaceuticals (Pvt) Ltd. Lahore Contract manufactured by M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Opizole 40mg Injection
	Composition	Each vial contains:- Omeprazole Sodium (Lyophilized) eq. to Omeprazole……40mg
	Diary No. Date of R& I & fee	Dy No. 3061, 14-05-2013, Rs.50000/-, 14-05-2013
	Pharmacological Group	Proton pump inhibitor
	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.	Omeprazole IV 40mg Injection of sandoz (TGA)
	Me-too status	Risek 40mg injection by Getz Pharma
	GMP status	GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Secretary RB apprised the Board that firm has changed their name to M/s A'raf Pharmaceuticals Lahore. The Board deferred the case for clarification regarding name of the firm **(M-265)**.
	Evaluation by PEC	The firm has submitted document of licensing division dated 11th November, 2013 for change of name of company to "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)". **GMP status of M/s A'raf (Pvt) Ltd could not be verified**.
	Decision: Deferred for submission of GMP status of "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)" and number of products already approved in contract manufacturing and details of section approved by CLB.	
1763.	Name and address of manufacturer / Applicant	M/s. Remedy Pharmaceuticals (Pvt) Ltd. Lahore Contract manufactured by M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Piprazo 4.50gm Injection
	Composition	Each vial contains:- Sterile Piperacillin Sodium eq. to Piperacillin ……4.0gm

		Sterile Tazobactam Sodium eq. to Tazobactam ……0.50gm
	Diary No. Date of R& I & fee	Dy No. 3062, 14-05-2013, Rs.50000/-, 14-05-2013
	Pharmacological Group	Penicillin antibiotic
	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.	Piperacillin Tazobactum by Sandoz (MHRA Approved)
	Me-too status	Tazocin 4.5gm by Wyeth Ltd
	GMP status	GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Secretary RB apprised the Board that firm has changed their name to M/s A'raf Pharmaceuticals Lahore. The Board deferred the case for clarification regarding name of the firm **(M-265)**.
	Evaluation by PEC	The firm has submitted document of licensing division dated 11th November, 2013 for change of name of company to "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)". **GMP status of M/s A'raf (Pvt) Ltd could not be verified**.
	Decision: Deferred for submission of GMP status of "M/s A'raf (Pvt) Ltd, 23-Km, Raiwind Road, Lahore (DML No.00685)" and number of products already approved in contract manufacturing and details of section approved by CLB.	
1764.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals, Plot No. 35, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Trend ophthalmic suspension
	Composition	Each ml contains: Neomycin (as sulphate)…….3500 IU Dexamethasone……1 mg Polymixin B sulphate…….6000 IU
	Diary No. Date of R& I & fee	Dy.No.124;(08-11-2016);Rs.20,000/-(08-11-2016)
	Pharmacological Group	Steroid, antibacterial agent
	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.	Maxitrol ophthalmic suspension (MHRA approved)
	Me-too status	Max-ND ophthalmic **solution** of M/s Polyfine Chempharma
	GMP status	Last GMP inspection conducted on 09-03-2017 and the report concludes that viewing the facts the company is following the GMP guidelines as of today.
	Previous remarks of the Evaluator.	The reference of me-too drug provided by the firm **Maxitrol eye drops** of M/s Novartis also contains • Hypromellose ……..0.5% **as active** • Neomycin (as sulphate)…….3500 IU • Dexamethasone……1 mg • Polymixin B sulphate…….6000 IU
	Previous decision(s)	Deferred for confirmation of hypermellose and solution / suspension in reference regulatory authorities **(M-277).** Deferred for further deliberation in view of reference product **(M-287)**.
	Evaluation by PEC	The firm has submitted that Hypermellose is not mentioned as active in label claim approved by Reference regulatory authorities and it is considered only as an excipient.

		The dosage form of reference product is in ophthalmic suspension. The firm has referred USP reference monograph of product is an ophthalmic suspension stating neomycin, polymyxin B Sulfate and dexamethasone as an active. Hypromellose is also not mentioned as API in any monograph of official compendium.
	Decision: Registration Board deferred the case for further deliberation in view of reference product.	
1765.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Plot No. 31, 32, Punjab Small Industrial Estate, Taxilla.
	Brand Name +Dosage Form + Strength	Wenoxime 200mg Capsules
	Composition	Each capsule contains:- Cefixime……200mg
	Diary No. Date of R& I & fee	Dy.No.8899, 17-01-2014, Rs.20,000/-, 17-01-2014
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1 × 5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Spanish Agency of Medicines and Health Products
	Me-too status	Suprax by Lupin Pharma Icef Capsule by ICI
	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.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of international availability in reference regulatory Authorities **(M-243 & M-250)**.
	Evaluation by PEC	The approval status of applied formulation has been confirmed in Spanish Agency of Medicines and Health Products.
	Decision: Approved.	
1766.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals (Pvt) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Vit.D 5mg/ml Injection
	Composition	Each 1ml ampoule contains: Cholecalciferol (200,000I.U).....5mg
	Diary No. Date of R& I & fee	Rs. 40,000/- (Duplicate Dossier)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	BP Spec's
	Pack size & Demanded Price	1ml x 5's
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 Good 200,000IU / 1 ml solution for injection of (ANSM France approved)
	Me-too status	Calciferol Injection M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 30-01-2018 and report concludes that firm may be considered to be operative in Good level of cGMP Compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following: **(M-282)** a. Revised Form-5 is submitted with following label claim: Each ml contains: Cholecalciferol…….5mg eq. to 250000 IU b. Clarification is required regarding calculation of 5mg eq. to 250000IU. c. Quantity of API submitted in master formulation is not rational with label claim.

		d. Reference of calcitrol (1mcg/ml) injection is given under evidence of availability in reference agencies and Pakistan.
	Evaluation by PEC	The firm has submitted revised Form-5 with fee challan of Rs. 5,000/- (Deposit slip#0802855) dated 09-01-2019. **Differential fee is required to be submitted.**
	Decision: Deferred for submission of differential fee for revision of formulation.	
1767.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals (Pvt) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Go-Spa Injection 40mg/ 2ml
	Composition	Each 2ml ampoule ontains:- Drotaverine HCl……..…40mg
	Diary No. Date of R& I & fee	Dy. No. 4118, 28-12-2016; Rs.20,000/- (28-12-2016)
	Pharmacological Group	Anti-Spasmodic
	Type of Form	Form-5
	Finished product Specification	in house specification
	Pack size & Demanded Price	25x2ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	**Not provided**
	Me-too status	No-Spa by Sanofi- Aventis
	GMP status	Last GMP inspection was conducted on 30-08-2018 and the report concludes: "The firm **MAY BE** considered to be operative in **GOOD** level of cGMP compliance. However, it was an old facility, over space is limited, workload is heavy due to heavy production of for local and export purposes. The firm should plan for modification and/ or shifting to wide area in future. They were also advised to arrange more fire-extinguishers and improve emergency exits in the building. They should also make a direct connection with fire brigade and install smoke detectors.
	Previous remarks of the Evaluator.	Inspection report includes many observations. The applied drug couldn't be searched in the reference regulatory authorities.
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by Registration Board in 275th meeting **(M-279)**.
	Evaluation by PEC	Following reference for drotaverine 40mg/2ml injection in three European countries along with reference weblink. 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved) (Link:https://www.ogyei.gov.hu/gyogyszeradatbazis/index.php?action=show_details&item=11235) Date of access: 09-11-2018 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) (Link:https://www.anm.ro/_/_RCP/RCP_6973_10.10.14.pdf) Date of access: 09-11-2018 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved) (Link:http://www.bda.bg/images/stories/documents/register/drugs/details/lf2120.htm) Date of access: 09-11-2018
	Decision: Approved with innovator's specifications.	

1768.	Name and address of manufacturer / Applicant	M/s NovaMed Pharmaceuticals Pvt. Ltd., 28-Km Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Vitamol-F Tablets
	Composition	Each Tablet contains:- Paracetamol …….650mg Orphenadrine Citrate ……50mg
	Diary No. Date of R& I & fee	Dy No. 806: 21-09-2015 PKR 20,000/-: 21-09-2015
	Pharmacological Group	Analgesic and muscle relaxant
	Type of Form	Form 5
	Finished product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	3 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nuberol Forte by Searle
	GMP status	GMP inspection dated 22-01-2019 concluded that the firm was considered to be operating at GOOD level of compliance with GMP guidelines.
	Previous remarks of the Evaluator.	• Latest GMP inspection report (which should have been conducted within the period of last one year) • Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 249th meeting
	Previous decision(s)	**Deferred for following submission (M-273)** • GMP inspection report conducted within a period of last 1 year. • Evidence of approval by reference regulatory authorities
	Evaluation by PEC	The firm has revised formulation with submission of fee challan of Rs.20,000/- (Deposit slip # 1900994) dated 27-03-2019. The new formulation is as below: Each tablet contains:- Paracetamol …….450mg Orphenadrine Citrate ……35mg **International availability:** Norgesic 35mg/ 450mg uncoated tablet of M/s iNova Pharmaceuticals**,** Approved in (TGA) Australia **Me-too status:** Gloral tablet of M/s Global Pharmaceuticals (Reg # 066681)**.**
	Decision: Approved with innovator's specifications and with following revision: **Each tablet contains:-** **Paracetamol …….450mg** **Orphenadrine Citrate ……35mg**	
1769.	Name and address of manufacturer / Applicant	M/s EG Pharmaceutical, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	TIZAREX Tablet 2mg
	Composition	Each tablet contains: Tizanidine as hydrochloride……2mg
	Diary No. Date of R& I & fee	26871, 29-12-2017, 20,000/-, 29-12-2017
	Pharmacological Group	Skeletal Muscle relaxant 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 2mg Tablet of Teva, UK **(MHRA approved)**
	Me-too status	Tandolax 2mg Tablet M/s High-Q Pharmaceuticals
	GMP status	GMP inspection conducted on 28-08-2018 & 03-09-2018

		concluded that M/s EG Pharma may be considered to be operating in compliance with GMP guidelines as per Drugs Act, 1976 and rules framed thereunder.
	Previous remarks of the Evaluator.	Salt form of applied formulation is not mentioned in Form-5. Clarification is required.
	Previous decision(s)	Deferred for revision of formulation with salt form of API as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt form and deposited fee challan of Rs.5,000/- (Deposit slip#0717200) dated 18-03-2019.
	Decision: Approved.	
1770.	Name and address of manufacturer / Applicant	M/s EG Pharmaceutical, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	DELORTA TABLET 5mg
	Composition	Each Film coated tablet contains: Desloratadine……5mg
	Diary No. Date of R& I & fee	26872, 29-12-2017, 20,000/-, 29-12-2017
	Pharmacological Group	Antihistamine
	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	Desdine 5mg Tablet of M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080821)
	GMP status	As recoded for above application
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised Form-5 from uncoated to Film coated tablet and deposited fee challan of Rs.5,000/- (Deposit slip#0717199) dated 18-03-2019.
	Decision: Approved with innovator's specifications.	
1771.	Name and address of manufacturer / Applicant	M/s EG Pharmaceutical, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	PITAVA 2MG TABLET
	Composition	Each tablet contains: Pitavastatin as calcium ……2mg
	Diary No. Date of R& I & fee	26867, 29-12-2017, 20,000/-, 29-12-2017
	Pharmacological Group	HMG-CoA reductase inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	PITALO 2mg Tablet of GENIX PHARMA
	GMP status	As recoded for above application
	Previous remarks of the Evaluator.	Salt form of API is not mentioned in label claim. Clarification/correction is required.
	Previous decision(s)	Deferred for revision of formulation with salt form of API as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with fee challan of Rs.5,000/- (Deposit slip#0505697) dated

		18-03-2019.
	Decision: Approved with innovator's specifications.	
1772.	Name and address of manufacturer / Applicant	M/s EG Pharmaceutical, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	SIGLIP TABLETS 50/1000MG
	Composition	Each film coated tablet contains: Sitagliptin as phosphate monhydrate……50mg Metformin Hydrochloride…….1000mg
	Diary No. Date of R& I & fee	26892, 29-12-2017, 20,000/-, 29-12-2017
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	14's/ As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	ARTG ID: 149023; JANUMET 50mg/1000mg film-coated tablet by M/s Merck Sharp & Dohme (Australia) Pty Ltd **Approved in TGA.**
	Me-too status	Neoglip 50/1000mg Tablets of M/s Atco Lab (Reg#053100)
	GMP status	As recoded for above application
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following: **(M-287)** • Revision of formulation with salt form of API as per reference product along with submission of requisite fee for change of formulation. • Submision of enclosures of Form-5
	Evaluation by PEC	The firm has submitted revised formulation as per reference with fee challan of Rs.5,000/- (Deposit slip#0740243) dated 18-03-2019.
	Decision: Approved with innovator's specifications.	
1773.	Name and address of manufacturer / Applicant	M/s EG Pharmaceutical, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Monticast 5mg Chewable tablet
	Composition	Each chewable tablet contains: Montelukast as Sodium …..5mg
	Diary No. Date of R& I & fee	Dy. No.26880; 29-12-2017; Rs.20,000/- (29-12-2017)
	Pharmacological Group	Leukotriene receptor antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 14's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Monty 10mg tablets of M/s Leads Pharma (Reg. # 050965)
	GMP status	As recoded for above application
	Previous remarks of the Evaluator.	Details of enclosures of Form-5 are missing. Revised Form-5 is required. • Master formulation shows film coating while reference product is chewable tablet. Clarification is required.
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised formulation as per reference with fee challan of Rs.5,000/- (Deposit slip#0505698) dated 18-03-2019.
	Decision: Approved.	
1774.	Name and address of manufacturer / Applicant	M/s EG Pharmaceutical, Plot No. 13-A, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	DENSETRON INJECTION 8MG/4ML (IM/IV)

	Composition	Each 4ml ampoule contains: Ondansetron as hydrochloride dihydrate……8mg
	Diary No. Date of R& I & fee	26893, 29-12-2017, 20,000/-, 29-12-2017
	Pharmacological Group	Antiemetic; Serotonin (5HT3) antagonists ATC Code: A04AA01
	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.	MHRA Approved
	Me-too status	Ondansetron –Sandoz 8mg / 4ml solution for injection of M/s Novartis (Reg#066121)
	GMP status	As recoded for above application
	Previous remarks of the Evaluator.	Salt form of API is not mentioned in Form-5. Revised Form-5 is required.
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised formulation as per reference with fee challan of Rs.5,000/- (Deposit slip#0505699) dated 18-03-2019.
	Decision: Approved.	
1775.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals, Plot No.3, Block I-II, Industrial Estate, hattar
	Brand Name +Dosage Form + Strength	Artiwel 120mg Injection
	Composition	Each vial contains: Artesunate……120mg
	Diary No. Date of R& I & fee	26819, 29-12-2017, 20,000/-, 28-12-2017
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1 vial with relevant solvent (WFI or Lignocaine); As per policy of MOH
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection 120mg of M/s Genix (Reg. # 076073)
	GMP status	GMP inspection conducted on 12-11-2018 concluded that the firm is operating at satisfactory level of GMP.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for clarification of diluent for applied formulation. Moreover Registration Board directed the firm to submit separate applications for registration of diluents **(M-287).**
	Evaluation by PEC	The firm has submitted that "We have wrongly mentioned in formulation. Our firm has separately applied for sodium bicarbonate 5% as a solvent."
	Decision: Approved with international pharmacopoeia specifications.	
1776.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir.
	Brand Name +Dosage Form + Strength	Clomison Tablet 50mg
	Composition	Each tablet contains:- Clomiphene Citrate……..50mg
	Diary No. Date of R& I & fee	Diary No. 6143, 24-09-2013, Rs.20,000/-.
	Pharmacological Group	Ovulatory stimulant
	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.	Clomid 50mg Tablets by M/s Sanofi , **(MHRA approved)**
	Me-too status	Ovafin 50 mg tablet by M/s OBS (Reg#019173)
	GMP status	Last inspection of Akson Pharmaceuticals was conducted on 16-06-2017 & 25-07-2017 for renewal of DML and panel recommended for renewal of DML.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred till decision on manufacturing requirement for clomiphene **(M-259)**.
	Evaluation by PEC	
	Decision: Registration Board decided to approve registration of applied 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.	
1777.	Name and address of manufacturer / Applicant	M/s Pearl Pharmaceuticals, Plot No.204, Street No.1, I-10/3 industrial Area, Islamabad
	Brand Name +Dosage Form + Strength	Trolim Ointment
	Composition	Each gram contains Tacrolimus as monohydrate…….. 0.03% w/w
	Diary No. Date of R& I & fee	Dy.No.2694, 17-01-2011, Rs.8,000/-, 17-01-2011 Rs.12,000/-, 13-04-2015
	Pharmacological Group	Immunomodulator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, Rs.325.00
	Approval status of product in Reference Regulatory Authorities.	Protopic 0.03% w/w ointment by M/s Astellas Ireland Co. Ltd (Netherlands Approved),
	Me-too status	Eczemus 0.03% Ointment by M/s Brookes Pharma (Reg#045494)
	GMP status	GMP inspection dated 23-07-2018 concluded that the firm was found in satisfactory compliance with GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of approval by reference regulatory authorities for decision regarding requirement of manufacturing facility for Tacrolimus **(M-268)**.
	Evaluation by PEC	• Firm has Cream/Ointment (Steroid, Non-Steroid) Section. • Approval status has been confirmed in Netherlands. • Registration Board decided to grant registration of above applied products 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.
	Decision: Registration Board decided to approve registration of applied formulation 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.	
1778.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals (Pvt) Limited, Plot # 3, Street no. S-5, National Industrial Zone Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Spix tablet 80mg/ 80mg
	Composition	Each film-coated tablet contains: Phloroglucinol Dihydrate ……80mg Trimethylphloroglucinol……80mg
	Diary No. Date of R& I & fee	Dy. No. 4080, 21-04-2017; Rs.20,000/- (19-04-2017)
	Pharmacological Group	Antispasmodics

	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x10's & as per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	**Approved by ANSM of France**
	Me-too status	Spadix 80mg/80mg tablets of M/s Tabros Pharma
	GMP status	Last GMP inspection was conducted on 08-06-2017 and the report concludes firm may be issued GMP certificate.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for clarification of dosage form since reference product is available as sugar coated tablet whereas firm has applied for film coated tablet **(M-279).** Deferred for submission of fee for revision of formulation **(M-283)**.
	Evaluation by PEC	The firm has submitted revised Form-5 with sugar coating in label claim and master formulation in line with reference country: Each sugar-coated tablet contains: Phloroglucinol Dihydrate…….....80mg Trimethylphloroglucinol……80mg The firm has deposited fee challan of Rs. 5,000/- (Deposit slip#0818783) dated 31-12-2018.
	Decision: Approved with innovator's specifications and with following revision: **Each sugar-coated tablet contains:** **Phloroglucinol Dihydrate…….80mg** **Trimethylphloroglucinol……80mg**	
1779.	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	Bucaine Injection
	Composition	Each 2ml ampoule contains: Bupivacaine hydrochloride……7.5mg
	Diary No. Date of R& I & fee	13456, 25-08-2017, 20,000/-, 23-08-2017
	Pharmacological Group	Local anesthetic agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2ml × 5's, 10's, 100's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Bupivacaine hydrochloride 15mg/2ml Injection of Aurobindo Pharms **(Health Canada)**
	Me-too status	Bucane Injection 7.5mg/ml of ophth Pharma (Reg#042023)
	GMP status	GMP inspection on 20-09-2017 concluded that overall condition of the firm is satisfactory.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th 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. **(M-284).** Deferred for submission of differential fee of Rs. 15,000/- for change of formulation. **(M-287)**
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with fee challan of Rs. 5000/- (deposit slip # 0771779) dated 18-12-2018. The correct formulation is as below: Each 2ml ampoule contains: Bupivacaine hydrochloride……15mg The firm has submitted differential fee of Rs. 15,000/- (deposit slip # 0841315) dated 21-02-2019 for revision of formulation.

	Decision: Approved with innovator's specifications and with following revision: **Each 2ml ampoule contains:** **Bupivacaine hydrochloride……15mg**	
1780.	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	Fosmin Gel
	Composition	Each gram Contains:- Isotretinoin……..0.05% w/w
	Diary No. Date of R& I & fee	R&I 1381, 04-03-2015, Rs.20,000/-
	Pharmacological Group	Retinoids for topical use in acne
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/10gm
	Approval status of product in Reference Regulatory Authorities.	Isotrex Gel 0.05% by M/s Stiefel Laboratories (MHRA approved)
	Me-too status	Iso Scot Gel 0.05% of M/s Scotman Pharma
	GMP status	GMP inspection on 20-09-2017 concluded that overall condition of the firm is satisfactory.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of approval by Reference Regulatory authorities / countries **(M-257)**.
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation for change of formulation from cream to gel. The firm has deposited fee challan of Rs. 5,000/- (deposit slip # 0841316) dated 21-02-2019 and fee challan of Rs. 15,000/- (Deposit slip # 1928016) dated 29-04-2019.
	Decision: Approved with innovator's specifications.	
1781.	Name and address of manufacturer / Applicant	M/s. Cibex (Private) Ltd., F-405, S.I.T.E, Karachi
	Brand Name +Dosage Form + Strength	Cibcos-R Syrup
	Composition	Each 5ml contains: Acefylline Piperazine……45mg Diphenhydramine……..…8mg
	Diary No. Date of R& I & fee	Dy. No. 607, 30-04-2014, Rs.20,000/-
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO/60ml, 120ml
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Acelyf Syrup of M/s Hicon Pharma
	GMP status	GMP Inspection of Cibex Pvt. Ltd conducted on 29-08-2017 with showed conclusive remarks of satisfactory level of cGMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for review of formulation by the Review Committee **(M-245)**.
	Evaluation by PEC	The firm has submitted that for cough preparation, condition of SRA has been waived.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.	
1782.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Private) Limited, Karachi
	Brand Name +Dosage Form + Strength	Wincip 250mg/5ml Granules for Oral Suspension.
	Composition	Dy. No. 504 dated 21-09-2015, Rs: 20,000/-
	Diary No. Date of R& I & fee	Each 5ml of reconstituted suspension contains:

<table>
<tr><td></td><td></td><td>Ciprofloxacin……..250 mg
Granules:-
Each 100mg Granules contains 22.5mg of Ciprofloxacin base.
Solvent/Diluent:
Soya lecithin, Medium chain triglycerides, Strawberry flavor, Sugar (Granular), Purified water.</td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Antibiotics</td></tr>
<tr><td></td><td>Type of Form</td><td>Form-5</td></tr>
<tr><td></td><td>Finished product Specification</td><td>Manufacture Specification</td></tr>
<tr><td></td><td>Pack size & Demanded Price</td><td>Pack size of 60 ml / as per price fixed by Government.</td></tr>
<tr><td></td><td>Approval status of product in Reference Regulatory Authorities.</td><td>Ciproxin-USFDA approved</td></tr>
<tr><td></td><td>Me-too status</td><td>Hiflox (Hilton)</td></tr>
<tr><td></td><td>GMP status</td><td>Oral Dry Powder Suspension (General) & Liquid Syrup (General) granted in 239th meeting of Central Licensing Board.</td></tr>
<tr><td></td><td>Previous remarks of the Evaluator.</td><td>--.</td></tr>
<tr><td></td><td>Previous decision(s)</td><td>Deferred for verification of composition of diluents in Registration Board (M-255).
Registration Board deferred the case as per decision of 269th meeting regarding formulation of “ciprofloxacin 125mg/5ml granules and solvent for oral suspension”. Wherein Registration Board was apprised that already registered products were either not providing diluent with the ciprofloxacin suspension or the composition of diluent was not as per the reference product. Registration Board advised Pharmaceutical Evaluation Cell to prepare the case along with details including manufacturing area requirements of the solvent/diluent and considering the legal requirements for the separate registration of the solvent for further deliberation in Registration Board
(M-270).
Deferred for clarification of applied formulation since reference product contains Ciprofloxacin as base only whereas submitted source contains Ciprofloxacin as hydrochloride granules (M-286).</td></tr>
<tr><td></td><td>Evaluation by PEC</td><td>• Firm has submitted detailed composition of diluent as under:
<table>
<tr><th>Sr.#</th><th>Raw Material</th><th>Req. volume per bottle</th></tr>
<tr><td>i.</td><td>Soya lecithin</td><td>0.45g</td></tr>
<tr><td>ii.</td><td>Medium chain triglycerides</td><td>0.500</td></tr>
<tr><td>iii.</td><td>Sugar (Granular)</td><td>3.31</td></tr>
<tr><td>iv.</td><td>Strawberry flavor</td><td>0.669</td></tr>
<tr><td>v.</td><td>Purified water</td><td>q.s 40.0 ml</td></tr>
</table>
• The above stated composition is qualitatively identical to that of reference product approved by USFDA.
• Source: M/s Vision Pharma
• The firm has submitted revised Form-5 and master formulation with fee challan of of Rs. 5,000/- (Deposit slip#0721179) dated 07-11-2018.</td></tr>
<tr><td></td><td colspan="2">Decision: Approved. Diluent shall be as per innovator’s composition.</td></tr>
<tr><td>1783.</td><td>Name and address of manufacturer / Applicant</td><td>M/s Winlet Pharma 30 Km, Laksian Lahore road. Sargodha</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>Lorades 2.5 mg/5ml Syrup</td></tr>
<tr><td></td><td>Composition</td><td>Each 5 ml contains:
Desloratadine ……0.5 mg</td></tr>
<tr><td></td><td>Diary No. Date of R& I & fee</td><td>Dy No. 3414, 13-04-2018, Rs.20,000/-</td></tr>
</table>

	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.	Clarinex syrup by Merck Sharp Dohm **(USFDA Approved)**
	Me-too status	Neo-Antial syrup by Sami Pharma
	GMP status	New DML granted Inspection Date 05/12/2017
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting **(M-282)**. Deferred for submission of 20,000/- fee for revision of applied strength **(M-288)**.
	Evaluation by PEC	The firm has submitted revised Form-5 as per reference formulation with following details: Each 5 ml contains: Desloratadine ……..2.5 mg **International availability:** Clarinex syrup by Merck Sharp Dohm (USFDA Approved) **Me-too status:** (Neo-antial syrup by Sami Pharma) Fee of 5000/-, challan # 0814955, dated: 31/12/2018 was submitted. The firm has submitted differential fee of Rs. 15,000/- (Deposit slip # 1916637) dated 09-05-2019.
	Decision: Approved with innovator's specifications.	
1784.	Name and address of manufacturer / Applicant	M/s Winlet Pharma 30 Km, Laksian Lahore road. Sargodha
	Brand Name +Dosage Form + Strength	Famole 40 mg/5ml Dry Suspension
	Composition	Each 5 ml contains: 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
	Approval status of product in Reference Regulatory Authorities.	Pepcid 40 mg/5 ml for suspension of Salix Pharma Inc., USA **(USFDA approved)**
	Me-too status	Pepnex 40mg/5ml Dry Powder Suspension of M/s Nexus Pharma
	GMP status	New DML granted Inspection Date 05/12/2017
	Previous remarks of the 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)
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting **(M-282)**. Deferred for submission of 20,000/- fee for revision of applied strength **(M-288)**.
	Evaluation by PEC	The firm has submitted revised Form-5 as per reference formulation with following details: Each 5 ml contains: Famotidine ……40 mg **International:** (Pepcid 40 mg/5 ml of Salix Pharma Inc., USA (USFDA approved) **Me-too status:** (Pepnex 40mg/5ml Dry Powder Suspension of M/s Nexus Pharma)

		Fee of 5000/-, challan # 0814954, dated: 31/12/2018 was submitted. The firm has submitted differential fee of Rs. 15,000/- (Deposit slip # 1916638) dated 09-05-2019.
	Decision: Approved.	
1785.	Name and address of manufacturer / Applicant	M/s Walt Danzay Pharmaceuticals, Plot No 35-A, Small Industrial Estate, Taxila, Pakistan
	Brand Name +Dosage Form + Strength	WaltDul Capsule 30 mg
	Composition	Each capsule contains: Enteric coated pellets of Duloxetine hydrochloride (17.5%) equivalent to Duloxetine……30mg
	Diary No. Date of R& I & fee	Dy No: 1396 : 03-05-2017 PKR 20,000/- : 03-05-2017
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor (SSRI)
	Type of Form	Form 5
	Finished product Specification	-
	Pack size & Demanded Price	14's As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Cymbalta by Lilly (**USFDA** Approved)
	Me-too status	Dulan by Hilton Pharma
	GMP status	Inspection report dated 15-02-2017, the panel recommended the grant of drug manufacturing license
	Previous remarks of the Evaluator.	Firm has claimed in house specifications while the product is present in USP • Firm has not provided source, GMP, COA and stability data of pellets
	Previous decision(s)	Deferred for following submissions **(M-271)** • Source of pellets • GMP of manufacturer of pellets • Certificate of analysis of pellets • Real time and accelerated stability study data of 3 batches of pellets • Differential fee (if pellets are imported) Submission of same brand name for all strengths Registration Board deferred for clarification as submitted source of pellets is not of USP grade **(M-275).** Registration Board deferred the case since submitted source of pellets is not of USP grade **(M-278).** Registration Board deferred the case since submitted source of pellets is not of USP grade **(M-285)**.
	Evaluation by PEC	Firm has requested to change the source of pellets (22.5%) to M/s Murli Krishna Pharma (Pvt) Ltd., along with fee PKR 100,000/- (Chalan # 0726014). Firm has also submitted COA and stability study data and copy of GMP certificate The real time stability study data of pellets is conducted at $25^{o}C \pm 2^{o}C$ and 60% ± 5% RH which is not as per the requirement of Zone IV-A. The USP has specified the pellets to be tested at buffer stage of either 20% or 32%, while the pellets of M/s Murli Krishna is 22.5%. The dissolution range of pellets in USP is NLT 75% of Q in 60 mins, while that provided in COA is NLT 70% of Q in 45 min. **New firm title is "M/s. Horizon Healthcare (Pvt.) Ltd, Taxila, Pakistan".** GMP certificate granted based on inspection conducted on 26-

		01-2018. The firm has submitted stability data sheet with revised storage conditions of 30°C ± 2°C and 65% ± 5%RH while remaining particulars i.e., batch numbers and results etc was the same. The firm has submitted fresh dossier with new title of the firm **"M/s. Horizon Healthcare (Pvt.) Ltd, Taxila, Pakistan"**. New fee challan of Rs. 20,000/- (deposit slip # 0817179) dated 05-12-2018 has been submitted. **Source of pellets**: M/s Murli Krishna Pharma (Pvt) Ltd, India. The firm has submitted revised COA from M/s Murli Krishna Pharma (Pvt) Ltd, India with dissolution specifications same as mentioned in USP.
	Decision: Approved.	
1786.	Name and address of manufacturer / Applicant	M/s Walt Danzay Pharmaceuticals, Plot No 35-A, Small Industrial Estate, Taxila, Pakistan
	Brand Name +Dosage Form + Strength	DulaxWalt 60 mg Capsule
	Composition	Each capsule contains Enteric coated pellets of Duloxetine hydrochloride (22.5%) equivalent to Duloxetine……60mg
	Diary No. Date of R& I & fee	Dy No: 3193 : 18-05-2017 PKR 20,000/- : 18-05-2017
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor (SSRI)
	Type of Form	Form-5
	Finished product Specification	-
	Pack size & Demanded Price	1 x 10's: As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Cymbalta by Lilly (**USFDA** Approved)
	Me-too status	Dulan by Hilton Pharma
	GMP status	Inspection report dated 15-02-2017, the panel recommended the grant of drug manufacturing license
	Previous remarks of the Evaluator.	Firm has claimed in house specifications while the product is present in USP •Firm has not provided source, GMP, COA and stability data of pellets •Firm has applied for different brand name for 30mg strength of same drug
	Previous decision(s)	Deferred for following submissions **(M-271).** • Source of pellets • GMP of manufacturer of pellets • Certificate of analysis of pellets • Real time and accelerated stability study data of 3 batches of pellets • Differential fee (if pellets are imported) Submission of same brand name for all strengths Registration Board deferred for clarification as submitted source of pellets is not of USP grade **(M-275)**. Registration Board deferred the case since submitted source of pellets is not of USP grade **(M-278)**. Registration Board deferred the case since submitted source of pellets is not of USP grade **(M-285)**.
	Evaluation by PEC	Firm has requested to change the source of pellets (22.5%) to M/s Murli Krishna Pharma (Pvt) Ltd., along with fee PKR 100,000/- (Chalan # 0726014). Firm has also submitted COA and stability study data and copy of GMP certificate The real time stability study data of pellets is conducted at 25°C ± 2 °C and 60% ± 5% RH which is not as per the requirement of Zone IV-A.

		The USP has specified the pellets to be tested at buffer stage of either 20% or 32%, while the pellets of M/s Murli Krishna is 22.5%. The dissolution range of pellets in USP is NLT 75% of Q in 60 mins, while that provided in COA is NLT 70% of Q in 45 min. **New firm title is "M/s. Horizon Healthcare (Pvt.) Ltd, Taxila, Pakistan".** GMP certificate granted based on inspection conducted on 26-01-2018. The firm has submitted stability data sheet with revised storage conditions of 30°C ± 2 °C and 65% ± 5% while remaining particulars i.e., batch numbers and results etc was the same. The firm has submitted fresh dossier with new title of the firm **"M/s. Horizon Healthcare (Pvt.) Ltd, Taxila, Pakistan"**. New fee challan of Rs. 20,000/- (deposit slip # 0817180) dated 05-12-2018 has been submitted. **Source of pellets**: M/s Murli Krishna Pharma (Pvt) Ltd, India. The firm has submitted revised COA from M/s Murli Krishna Pharma (Pvt) Ltd, India with dissolution specifications same as mentioned in USP.
	Decision: Approved.	
1787.	Name and address of manufacturer / Applicant	M/s ISIS Pharmaceuticals and chemicals 25/1-3 sector 12-C, North Karachi industrial area, Karachi
	Brand Name +Dosage Form + Strength	Isaline 0.9% 100ml Infusion
	Composition	Each vial contains: Normal Saline…….5% 100ml
	Diary No. Date of R& I & fee	Dy.No.1715, 30-8-2016, Rs.20,000/-
	Pharmacological Group	Electrolyte solution
	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.	Sodium Chloride 0.9% Intravenous Infusion by M/s Eastgate Way (MHRA)
	Me-too status	Lifesol IV Infusion by M/s Geofman
	GMP status	Last GMP Inspection dated 12-6-17 with conclusive remarks of good cGMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for clarification of composition as firm has mentioned Normal saline instead of Sodium chloride in Form 5 and master formulation. Details of container closure system (glass or plastic) are required **(M-275)**.
	Evaluation by PEC	● The firm has submitted that ●"Due to some typographical error the composition of the product was mentioned as Normal saline 0.9% instead of sodium chloride 0.9%." ●Now the firm has submitted revised Form-5 with following label claim: ●Each vial contains: Sodium chloride……0.9% ●100ml vial (Infusion packed in plastic bottles) ●The firm has deposited fee challan Rs. 20,000/- (Deposit slip#0610570) dated 28-11-2018. (photocopy attached)
	Decision: Registration Board approved the formulation with following revision: **Each vial contains:** **Sodium chloride……0.9%**	

1788.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories, 21km Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	SUNDROP Oral Drops
	Composition	Each 10ml contains: Cholecalciferol…..…….5mg
	Diary No. Date of R& I & fee	Dy. No.625, R&I Dated 11.12.2014, Rs. 20,000/-
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs
	Pack size & Demanded Price	1x10ml,1x30ml &Rs.700/pack of 10ml,Rs.2000/pack of 30ml
	Approval status of product in Reference Regulatory Authorities.	**Finnish Medicine Agency**
	Me-too status	Doplet Oral Drops of M/s Saffron Pharma (Reg#078963)
	GMP status	GMP inspection conducted on 31-05-2018 to 01-06-2018 concluded that the firm has improved the documentation regarding production, QC and QA and the firm has installed a new HPLC (gradient system) and double beam UV spectrophotometer.
	Previous remarks of the Evaluator.	The composition of the proposed drug is incorrectly mentioned in Form-5 as "each 10 ml contains cholecalciferol 5mg/10ml" is written. Moreover, brand name resembles the other firms' drug.
	Previous decision(s)	Deferred for evidence of approval in reference agencies and me-too status. Moreover, the proposed composition of the drug needs to be verified since both strengths 5mg/10ml and 5mg/ml are mentioned in the dossier. **(M-271)**. Deferred for confirmation of approval status of applied formulation in reference regulatory authorities/agencies and their generic / me-too status **(M-275).**
	Evaluation by PEC	• Firm has clarified the proposed strength as 5mg/10ml (eq. to 20,000 IU/ml or 0.5mg cholecalciferol / ml). • The submitted me-too reference "Doplet-Oral Drops of M/s. Saffron Pharma" has been verified. • The approval status of applied formulation has been confirmed in **Finnish medicine agency**. • The firm has submitted fee challan of Rs. 5,000/- (deposit slip # 0811091) dated 25-04-2019.
	Decision: Approved with innovator's specifications.	
1789.	Name and address of manufacturer / Applicant	M/s. Hamaz Pharmaceuticals (Pvt.) Ltd, 13-Km, Bosan Road, Lutfabad Multan
	Brand Name +Dosage Form + Strength	ZEETOP 20mg Tablets
	Composition	Each dispersible tablet Contains:- Zinc Sulphate Monohyrate USP eq. to ….20mg elemental Zinc.
	Diary No. Date of R& I & fee	351, 03.03.2015, Rs.8000/-, Rs.12000/-, 02-03-2015
	Pharmacological Group	Indirectly-acting sympathomimetic
	Type of Form	Form-5
	Finished product Specification	International pharmacopoea
	Pack size & Demanded Price	1*10's; As per brand leader
	Approval status of product in Reference Regulatory Authorities.	WHO approved formulation
	Me-too status	Zindigi by Zafa Pharmaceuticals
	GMP status	GMP inspection dated 17-01-2018 concluded as follows: In view of all the above it is observed that the management has addressed most of the short comings, which were pointed out during the last inspection which leads the panel of inspectors to

		the conclusions that the firm is presently operating at satisfactory level of GMP compliance. M/s Hamaz Pharmaceuticals is situated at Multan hence it is advised to the management to continue their efforts to further upgrade their systems.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation of dosage form whether dispersible tablet or otherwise. **(M-266)**
	Evaluation by PEC	The firm has submitted revised master formulation for dispersible tablet. However, fee for such revision not submitted.
	Decision: Deferred for submission of fee for revision of formulation.	
1790.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot # 154, Sector 23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Flexibon Delayed Release Tablet
	Composition	Each delayed release tablet contains Diclofenac Sodium (enteric coated)……..50mg Misoprostol (1% w/w dispersion HPMC)……200mcg
	Diary No. Date of R& I & fee	Dy. No. 168 dated 17-09-2011 & 10-04-2014Rs. 20,000/-
	Pharmacological Group	NSAID/ Prostaglandin
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	20‘s Rs. 350/-
	Approval status of product in Reference Regulatory Authorities.	Arthrotec 50 modified release tablets of Pfizer **(MHRA approved)**
	Me-too status	Cytopan 50mg tablet of M/s GETZ Pharma (Reg#039729)
	GMP status	GMP inspection dated 20-03-2018 is considered to be operating at an acceptable level of compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for completion of application w.r.t following Shortcomings **(M-256)**:- To furnish approval status of same dosage form in reference regulatory authorities. To submit complete dosage form alongwith quantities of salt and base in master formulation per unit dose and per batch. To furnish master formulation with amount of base as well as salt per unit dose and per batch. Official monographs/reference pharmacopeia required for active and inactive ingredient in the master formulation. Reference of finished product specification alongwith procedure of analysis. Deferred for the clarification of manufacturing outline as in reference regulatory authorities **(M-283)**.
	Evaluation by PEC	The firm has submitted complete master formulation stating enteric coated Diclofenac sodium and Misoprostol (1% dispersion w/w in HPMC). The firm has submitted fee challan of Rs. 5,000/- (Deposit slip#0308598) dated 13-02-2019. However, the firm has not clarified the manufacturing outline.
	Decision: Deferred for clarification of manufacturing outline for applied formulation.	
1791.	Name and address of manufacturer / Applicant	M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Fuzo SR Tablet 10mg
	Composition	Each tablet contains:- 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 specifications
	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)** • Commitment as per 251st meeting of RB is required. • Availability in SRA is not provided by the firm. • Reference literature for detailed specification and analytical method is required. • Latest Inspection Report is required. Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)**. Deferred for revision of formulation and label claim as per the reference regulatory authorty approved reference product **(M-288)**.
	Evaluation by PEC	The firm has submitted following: Commitments as per 251st meeting of RB are required. The formulation is approved in MHRA. The firm has submitted in-house specs and detail of analytical method. The firm has submitted revised master formulation with correct label claim as below: Each extended release tablet contains:- Alfuzosin Hydrochloride……10mg Fee challan of Rs. 5,000/- (Deposit slip # 1916772) dated 06-05-2019 has been submitted.
	Decision: Registration Board approved with innovator's specifications and with following revision: **Each extended release tablet contains:-** **Alfuzosin Hydrochloride……10mg**	
1792.	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:- Iron Protein Succinylate……..20mg 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)** • Commitment as per 251st meeting of RB is required. • Availability in SRA is not provided by the firm. • Reference literature for detailed specification and analytical method is required.

		• Latest Inspection Report is required. Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. **(M-285)** Deferred for submission of fee for revision of formulation **(M-288)**.
	Evaluation by PEC	The firm has submitted following: Commitments as per 251st meeting of RB are required. The firm has submitted revised Form-5 stating label claim as below: Each film coated tablet contains:- Iron Protein Succinylate eq. to elemental Iron…..20mg Folic acid……..…2.5mg The firm has submitted in-house specs and detail of analytical method. The firm has submitted fee challan of Rs. 20,000/- (Deposit slip# 1916775) dated 06-05-2019.
	Decision: Approved with innovator's specifications.	
1793.	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	**In-ORS Solution 500ml**
	Composition	Each 500 ml contains: Sodium Chloride ……1.75gm Trisodium Citrate Trihydrate ……..1.45gm Potassium Chloride ……..0.75gm Glucose Anhydrous ……..10gm
	Diary No. Date of R& I & fee	Diary No: 13910, 30/08/2017, Rs: 20,000/-
	Pharmacological Group	Electrolyte
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1'sx500ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Standard ORS formulation
	Me-too status	Pedinex Oral Rehydration Solution by M/s Nexus Pharma (Pvt) Ltd (Reg#057883)
	GMP status	**10-06-2017** New License
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation whether applied formulation is preservative free or not. **(M-277)** Deferred for confirmation of terminal sterilization method for applied formulation. **(M-286)**
	Evaluation by PEC	• The firm has submitted that we have removed "Sodium benzoate" from our formulation and our new formulation for this product is free from preservative. • The firm has submitted fee challan of Rs.5000/-, (Deposit slip#0808315) dated 05-11-2018 for revision of formulation. • The liquid is filled under the area of laminar flow hood in polypropylene bottle immediately sealed. • Bottle are sterilized in autoclave with steam upto 100oC for 3 hours and pressure 1 to 2 bars. • GMP inspection conducted on 06th February, 2019 concluded that keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD.
	Decision: Deferred for confirmation of capacity of autoclave for terminal sterilization.	

Case no. 02 Registration applications of newly granted DML or New section (Human)

a. New DML

M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar

CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML # 000900 by way of formulation with following sections:

Tablet General Section: (10molecules/21products)
Cream/Ointment (General) section: (8molecules/ 8products)
Liquid ampoule (General) section: (10molecules/ 10products)
Dry Powder vial (General) section: (6molecules/ 8products)
Oral Powder Suspension (General) section (4molecules/ 4products)
Sachet (General) Section: (1molecule/ 1product)
Ophthalmic (General) Drop Section
Capsule section (General)

Tablet General section (10molecules/ 21products)		
1794.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Athapine 10/160mg Tablet
	Composition	Each film coated Tablet contains:- Amlodipine as besylate……10mg Valsartan.....160mg
	Diary No. Date of R& I & fee	14928, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Calcium channel blocker+ Angiotensin receptor blockers
	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.	Exforge Tablet (USFDA Approved)
	Me-too status	Co-Valzaar 10mg/160mg Tablet by M/s Vision Pharma
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Remarks of the Evaluator.	
	Decision: Approved.	
1795.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Athapine 5mg/160mg Tablet
	Composition	Each film coated Tablet contains:- Amlodipine as besylate……5mg Valsartan.....160mg
	Diary No. Date of R& I & fee	14918, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Calcium channel blocker+ Angiotensin receptor blockers
	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.	Amlodipine/Valsartan 5mg/160 mg tablet (MHRA Approved)
	Me-too status	Exforge Tablet of M/s Novartis Pharma (Reg # 047570)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	

1796.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Athapine 10mg/80mg Tablet
	Composition	Each film coated Tablet contains:- Amlodipine as besylate ……10mg Valsartan.....80mg
	Diary No. Date of R& I & fee	14898, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Calcium channel blocker+ Angiotensin receptor blockers
	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.	Not confirmed
	Me-too status	Not confirmed
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for following: **Evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.** **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1797.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Athapine 5mg/80mg Tablet
	Composition	Each film coated Tablet contains:- Amlodipine as besylate……5mg Valsartan.....80mg
	Diary No. Date of R& I & fee	16656, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Calcium channel blocker+ Angiotensin receptor blockers
	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.	Exforge Tablet By Novartis USFDA Approved
	Me-too status	Exforge tablet by M/s Novartis
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1798.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Atro 10/40mg Tablet
	Composition	Each film coated tablet contains; Ezetimibe……...10 mg Atorvastatin……...40 mg
	Diary No. Date of R& I & fee	16525, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	HMG-CoA reductase inhibitor and other lipid modifying agents
	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.	USFDA Approved.
	Me-too status	Atozet 10/40 tablet of M/s Hilton Pharma
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Salt form of atorvastatin is not mentioned. Revision of Form-5 with requisite fee is required.

		You have claimed BP and innovator's specifications simultaneously for your finished product. Clarification is required.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Clarification of finished product specifications of applied formulation.**	
1799.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Atro 10/20mg Tablet
	Composition	Each film coated tablet contains; Ezetimibe…….10mg Atorvastatin…….20mg
	Diary No. Date of R& I & fee	16545, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Lipid lowering Agent
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Atozet 10/20 tablet of M/s Hilton Pharma (Reg#061223)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Salt form of atorvastatin is not mentioned. Revision of Form-5 with requisite fee is required. You have claimed BP and innovator's specifications simultaneously for your finished product. Clarification is required.
	Decision: Deferred for following: • **Revision of formulation as per reference product along with submission of requisite fee.** • **Clarification of finished product specifications of applied formulation.**	
1800.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultostat 40mgTablets
	Composition	Each film coated tablet contains; Febuxostat……40 mg
	Diary No. Date of R& I & fee	16543, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-gout preparations (preparations inhibiting uric acid production)
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	ZURIG 40mg TABLETS GETZ PHARMA
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1801.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultostat 80mgTablets
	Composition	Each film coated tablet contains; Febuxostat…….80 mg
	Diary No. Date of R& I & fee	16554, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-gout preparations (preparations inhibiting uric acid production)
	Type of Form	Form-5
	Finished product Specification	Innovator'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	Febuxin by M/s AGP, Karachi (Reg. No. 081105)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1802.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Lokosa 100mg Tablet
	Composition	Each film coated tablet contains; Lacosamide……..…100mg
	Diary No. Date of R& I & fee	14912, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antiepileptics, other antiepileptics, ATC code N03AX18
	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.	Lacosamide Aspire 100 mg film-coated tablets by M/s Aspire Pharma Limited **(MHRA Approved)**
	Me-too status	Lalap 100mg Tablet by M/s Genix Pharma (Pvt.) Ltd (Reg#070471)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1803.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Losa 50mg Tablet
	Composition	Each film coated tablet contains; Lacosamide……..…50mg
	Diary No. Date of R& I & fee	14913, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antiepileptics, other antiepileptics, ATC code: N03AX18
	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.	MHRA Approved
	Me-too status	Lacolep 50mg by Hilton Pharma
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1804.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Adyzil 400mg Tablet
	Composition	Each film coated tablet contains; Linezolid……..……..400mg
	Diary No. Date of R& I & fee	16504, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Oxazolidinone antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator's 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	As recoded for above application
	Remarks of the Evaluator.	Master formulation does not contain ingredients for film

		coating. Correction is required.
	Decision: Deferred for revision of master formulation as per reference formulation alongwith requisite fee.	
1805.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Adyzil 600mg Tablet
	Composition	Each film coated tablet contains; Linezolid……..…600mg
	Diary No. Date of R& I & fee	16532, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Innovator'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	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1806.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultaxe 4mg Tablets
	Composition	Each film coated tablet contains; Lornoxicam……..4mg
	Diary No. Date of R& I & fee	14932, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	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	Acabel 4mg Tablet by M/s Continental Pharma (R#061603)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	The product name mentioned on fee challan is Thiocolchicoside 4mg while product name mentioned on Form-5 is Aultaxe 4mg Tablet.
	Decision: Approved.	
1807.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultaxe 8mg Tablets
	Composition	Each film coated tablet contains; Lornoxicam……..8mg
	Diary No. Date of R& I & fee	16503, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NOXON 8 mg film-coated tablets. (**AIFA approved**)
	Me-too status	Lornoxi DS 8mg Tablet. Reg. No. 74933
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1808.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rispron 1mg Tablets

	Composition	Each film coated tablet contains; Risperidone……..…1mg
	Diary No. Date of R& I & fee	16512, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antipsychotic
	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 by MHRA of UK
	Me-too status	Tablet Resjun -1 of M/s Jupiter Pharma Islamabad. (Reg.# 081921)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1809.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rispron 2mg Tablets
	Composition	Each film coated tablet contains; Risperidone……..…2mg
	Diary No. Date of R& I & fee	16514, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antipsychotic
	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.	MHRA Approved
	Me-too status	Riss 2mg tablet of M/s Shawan Pharma (Reg. # 080378)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1810.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Rispron 4mg Tablets
	Composition	Each film coated tablet contains; Risperidone……..…4mg
	Diary No. Date of R& I & fee	16516, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antipsychotic
	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.	MHRA Approved
	Me-too status	Riss 4mg tablet of M/s Shawan Pharma (Reg. # 080376)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1811.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	CITA 50/500mg Tablets
	Composition	Each film coated Tablet contains: Sitagliptin……..50 mg Metformin……500 mg
	Diary No. Date of R& I & fee	16510, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	specifications

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET™ (sitagliptin/metformin HCl) tablets USFDA Approved
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Salt forms of sitagliptin and metformin are not mentioned. Revision of Form-5 with requisite fee is required. Brand name mentioned in master formulation is CITAWEL which is different from that mentioned in Form-5. Clarification is required. Product name mentioned in finished product specification part is CITAWEL Tablet. Clarification is required.
	Decision: Deferred for following: • **Revision of formulation as per reference product alongwith requisite fee.** • **Clarification of brand name of applied formulation.**	
1812.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	CITA 50/1000mg Tablet
	Composition	Each film coated Tablet contains: Sitagliptin…….50 mg Metformin……1000 mg
	Diary No. Date of R& I & fee	16499, 07-03-2019, 20,000/-, 07-03-2019
	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.	ARTG ID: 149023; JANUMET 50mg/1000mg film-coated tablet by M/s Merck Sharp & Dohme (Australia) Pty Ltd (**Approved in TGA).**
	Me-too status	Neoglip 50/1000mg Tablets of M/s Atco Laboratories Ltd **(Reg#053100)**
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Salt forms of sitagliptin and metformin are not mentioned. Revision of Form-5 with requisite fee is required. Brand name mentioned in master formulation is CITAWEL which is different from that mentioned in Form-5. Clarification is required. Brand name mentioned in specification part is CITAWEL. Clarification is required.
	Decision: Deferred for following: • **Revision of formulation as per reference product alongwith requisite fee.** • **Clarification of brand name of applied formulation.**	
1813.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultolax 4 mg Tablets
	Composition	Each film coated tablet contains; Thiocolchicoside……..4 mg
	Diary No. Date of R& I & fee	14932, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Innovator specification
	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 ANSM (France) as uncoated tablet
	Me-too status	Wodnik 4mg tablet of M/s Martin Dow (Reg. # 081138)
	GMP status	As recoded for above application

	Remarks of the Evaluator.	Approved in ANSM (France) as uncoated tablet while it is applied as film-coated. Fee challan mentions capsule dosage form while submitted Form-5 suggests tablet dosage form.
	Decision: Deferred for following: • **Revision of formulation as per reference product alongwith requisite fee.** • **Clarification of dosage form in Form-5.**	
1814.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	M-Cobo 500 mcg/ Tablet
	Composition	Each film coated tablet contains; Mecobalamin …….500 mcg
	Diary No. Date of R& I & fee	16527, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specification	JP specifications
	Pack size & Demanded Price	2 × 10's; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Approved by PMDA of Japan
	Me-too status	Mecomed 500mcg by Global Pharma (Reg. No. 041670)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	In contrary to reference product approved by PMDA of Japan, which is available as sugar coated tablet, firm has applied for film coated tablet.
	Decision: Deferred for revision of formulation as per reference product alongwith requisite fee.	
Cream/Ointment (General) section (8molecules/ 8products)		
1815.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Dermo 0.05% Cream
	Composition	Each tube contains: Clobetasol propionate……..0.05%
	Diary No. Date of R& I & fee	14899, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	15g & 30g; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	ClobaDerm 500 micrograms/g Cream by Auden Mckenzie (Pharma Division) Ltd. (MHRA approved)
	Me-too status	Clobicare Cream by Martin Dow Pharmaceuticals (Reg# 067938)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1816.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Omegga Cream 0.1%
	Composition	Each tube contains: Momeggasone……..0.1%
	Diary No. Date of R& I & fee	14924, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	5g & 15g; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Momeggaderm Cream of Neophar Pharma

		(Not confirmed)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies adopted by the Registration Board in 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1817.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Mycin Vaginal Cream 2.0%
	Composition	Each gram contains: Clindamycin as phosphate……..2.0%
	Diary No. Date of R& I & fee	16523, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antibiotic
	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.	Cleocin **(USFDA approved)**
	Me-too status	Clindanor 2% cream of M/s Nortech pharmaceuticals
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1818.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Fusihyd Cream 15g
	Composition	Each gram cream contains: Fusidic Acid ……..20mg (2%) Hydrocortisone…….10mg (1%)
	Diary No. Date of R& I & fee	16497, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin H Cream (UK MHRA Approved)
	Me-too status	Melas H Cream of M/s Atco Laboratories
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Salt form of Hydrocortisone is not mentioned in Form-5. Revision of Form-5 with applicable fee is required.
	Decision: Deferred for revision of formulation as per reference product alongwith requisite fee.	
1819.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Terbilet Cream 1.0%
	Composition	Each gram contains: Terbinafine……1.0%
	Diary No. Date of R& I & fee	16533, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	5g & 10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Bina 1.0% Cream by M/s Linta pharmaceuticals (Pvt) Limited , Islamabad (Reg.# 080268)

	GMP status	As recoded for above application
	Remarks of the Evaluator.	Salt form of Terbinafine is not mentioned in Form-5. Revision of Form-5 with applicable fee is required.
	Decision: Deferred for revision of formulation as per reference product alongwith requisite fee.	
1820.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Salic Acid Ointment
	Composition	Each tube contains: Salicyclic acid ……..2.0 % w/w
	Diary No. Date of R& I & fee	14920, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Salicylate
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	15g & 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Salicylic acid Ointment 2.0% of Thornton and Ross **(MHRA approved**)
	Me-too status	Movelat ointment of ATCO (Not confirmed)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Evidence of applied formulation already approved (generic/me-too) by DRAP /DCO 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.	
1821.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Dyclin Gel 50gm
	Composition	Each tube contains: Diclofenac Diethylamine…….1.16%
	Diary No. Date of R& I & fee	16547, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	15g & 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (Voltarol 1.16% Emulgel) 10grams / 20grams)
	Me-too status	Voltral emulgel of M/s GSK (Pvt.) Ltd. (Reg.# 083991)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Label claim of applied formulation is not as per reference product. Revision of Form-5 with applicable fee is required.
	Decision: Deferred for following: **Revision of formulation as per reference formulation alongwith requisite fee.** **Clarification regarding required manufacturing facility since section is of cream/ointment while applied formulation is gel.**	
1822.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Permet 5% Lotion
	Composition	Each ml contains: Permethrin……50mg
	Diary No. Date of R& I & fee	16493, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Scabicide
	Type of Form	Form-5
	Finished product Specification	Innovator's specification
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Permethrin Lotion 5% w/w by M/s GlaxoSmithKline Consumer Healthcare (UK) Trading Limited (MHRA Approved)
	Me-too status	Nedax Plus Lotion of M/s Stiefel (Reg#037852)

	GMP status	As recoded for above application
	Remarks of the Evaluator.	The applied formulation does not specify whether the formulation is w/w or w/v.
	Decision: Deferred for clarification regarding required manufacturing facility since section is of cream/ointment while applied formulation is lotion.	
Liquid ampoule (General) section (10molecules/ 10products)		
1823.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	ARO Injection 5ml
	Composition	Each 5ml amber glass ampoule contain: Iron Sucrose eq. to elemental iron……..100mg
	Diary No. Date of R& I & fee	16540, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antianeamic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	5ml × 5's; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Venofer Injection by Vifor (MHRA Approved)
	Me-too status	Vortex 100mg/ 5ml injection of Saturn Pharma
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1824.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultaxe 8mg/2ml Injection
	Composition	Each injection contains: Lornoxicam (lyophilized) …….8mg
	Diary No. Date of R& I & fee	16505, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's vial; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (Austria Approved)
	Me-too status	Zafon 8mg injection of M/s Getz
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Rejected as firm doesnot have manufacturing facility.	
1825.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Atrawel 50mg / 5ml Injection
	Composition	Each ampoule contains: Atracurium Besylate……..50mg
	Diary No. Date of R& I & fee	16489, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	5ml × 5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA
	Me-too status	Atrium Injections by M/s Searle Pakistan, Karachi (Reg#053342)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	

1826.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	CITIL Injection
	Composition	Each ampoule contains: Citicoline sodium……250mg (250mg/2ml)
	Diary No. Date of R& I & fee	16537, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Psychostimulants and nootropics
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	2ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CITICOLINE PANPHARMA 250 mg / 2 ml solution for injection (IM, IV) ampoule by M/s PANPHARMA (ANSM, France Approved)
	Me-too status	Cerebolin Injection 250mg/2ml by M/s Zam Zam (Reg#021969)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Decision: Registration Board deferred the case for justification of 3% overage in master formulation.	
1827.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Irofer 500mg /10ml injection
	Composition	Each ampoule of 10ml contains: Iron as ferric carboxymaltose…….500mg
	Diary No. Date of R& I & fee	14901, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	10ml × 1's; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Ferinject Injectable 10ml vial of M/s M/s. RG Pharmaceutica (Pvt.) Ltd., (Reg.# 072548)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Decision: Registration Board deferred the case for justification of 3% overage in master formulation.	
1828.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Athonate 50mg/5ml Injection
	Composition	Each ampoule contains: Calcium folinate…….50mg
	Diary No. Date of R& I & fee	14935, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Detoxyfying agent for antineoplastic treatment ATC code: V03AF03
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	5ml × 5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Leucovorin Calcium Of (TGA Approved)
	Me-too status	Kunyrin 50mg/5ml Injection By Al-Habib (Reg. No. 021041)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	

1829.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Acobal 1ml injection
	Composition	Each 1ml injection contains: Mecobalamin……500mcg
	Diary No. Date of R& I & fee	14934, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	1ml; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	PMDA approved
	Me-too status	Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical
	GMP status	As recoded for above application
	Remarks of the Evaluator.	R & I date mentioned is 07-09-2019 and date mentioned on fee challan is 07-06-2019. Brand name mentioned on fee challan is Acobalamin while that mentioned on Form-5 is Acobal 1ml Injection. Pharmacological group is not written on Form-5. 3% Overage is mentioned in master formulation.
	Decision: Deferred for clarification of brand name on fee challan and justification of 3% overage in master formulation.	
1830.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Kitax Injection 1ml
	Composition	Each 1ml amber glass ampoule contain: Ketorolac Tromethamine……30mg / ml
	Diary No. Date of R& I & fee	16516, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml × 5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Toradol Injection of Atnahs Pharma, UK (MHRA Approved)
	Me-too status	Toralac Injection 30mg/ml by M/s Vision Pharma(R#050290)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Decision: Registration Board deferred the case for justification of 3% overage in master formulation.	
1831.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	AT-D Injection 1ml
	Composition	Each 1ml amber glass ampoule contain: Cholecalciferol……..5mg
	Diary No. Date of R& I & fee	16531, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	1ml × 1's; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 BON of Bouchara, ANSM Approved
	Me-too status	GET-D of GETZ Pharma Pakistan
	GMP status	As recoded for above application
	Remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Decision: Registration Board deferred the case for justification of 3% overage in master formulation.	

1832.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ondansetron Injection 8mg/4ml
	Composition	Each 4ml amber glass ampoule contain: Ondansetron as hydrochloride dihydrate……8mg
	Diary No. Date of R& I & fee	16498, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	4ml ×5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8mg/4ml solution for injection **(MHRA approved)**
	Me-too status	Zofran 8mg/4ml injection of M/s GSK
	GMP status	As recoded for above application
	Remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Decision: Registration Board deferred the case for justification of 3% overage in master formulation.	
Dry Powder vial (General) section: (6molecules/ 8products)		
1833.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	D-Cript 120mg injection
	Composition	Each vial contains: Artesunate……120mg
	Diary No. Date of R& I & fee	16524, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	IP specification
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified formulation
	Me-too status	Gen-M Injection 120mg of M/s Genix (Reg. # 076073)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Dry Powder vial (General) section
	Remarks of the Evaluator.	
	Decision: Approved.	
1834.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	E-Cript 60mg Injection
	Composition	Each vial contains: Artesunate……..60mg
	Diary No. Date of R& I & fee	16544, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	IP specifications
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	WHO Prequalified formulation
	Me-too status	Gen-M Injection 60mg of M/s Genix (Reg # 047630)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1835.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Vanco 500mg Injection

	Composition	Each vial contains: Vancomycin hydrochloride……..500mg
	Diary No. Date of R& I & fee	14911, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Glycopeptide antibacterial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Vancomycin 500mg Powder for Concentrate for Solution for Infusion by M/s Actavis UK Ltd, MHRA approved.
	Me-too status	Vancomycin 500mg Vial by M/s Abbott (Reg#015015)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Brand name mentioned on fee challan is different from that mentioned in Form-5. Correction is required.
	Decision: Approved.	
1836.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Vanco 1gm Injection
	Composition	Each vial contains: Vancomycin hydrochloride……1gm
	Diary No. Date of R& I & fee	16509, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Tricyclic glycopeptide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Vancomycin, 1000 mg, Powder for concentrate for solution for infusion of Hikma Pharam **(MHRA approved)**
	Me-too status	Vancotech Dry Powder Injection of Fynk Pharma (Reg # 081268)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1837.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Colomat 1million IU /vial Injection
	Composition	Each vial contains: Colistimethate sodium eq. to Colistimethate (lyophilized powder)……..1MIU
	Diary No. Date of R& I & fee	16534, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antibiotic (polymixin) ATC code: A07J01XB01
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Colistat Injection of M/s Medisure Lab (Reg#076160)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Label claim is not as per reference formulation which is colistimethate sodium……..1MIU while you have applied colistimethate ……1MIU.
	Decision: Deferred for evidence of approval of manufacturing facility for Dry Powder Lyophilized injectable section.	
1838.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Purple Injection 40mg
	Composition	Each vial contains: Esomeprazole as sodium (lyophilized powder) ……40mg

	Diary No. Date of R& I & fee	16541, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nexum Injection 40mg of M/s Getz Pharma (Reg. # 050651)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1839.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Peptun 40mg injection
	Composition	Each vial contains: Pantoprazole as sodium (Lyophilized powder)……..40mg
	Diary No. Date of R& I & fee	14915, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Pazole Dry Powder Injection IV 40mg of M/s Fynk pharmaceuticals
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
1840.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Dysozole 40mg Injection/ Infusion
	Composition	Each vial contains: Omeprazole as sodium (Lyophilized powder)……40mg
	Diary No. Date of R& I & fee	14900, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Risek 40mg Infusion by Getz
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved.	
Oral Powder Suspension (General) section (4molecules/ 4products)		
1841.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Linzal Dry Suspension 100mg/5ml
	Composition	Each 5ml suspension contain: Linezolid…….100mg
	Diary No. Date of R& I & fee	16506, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml; As fixed by Govt
	Approval status of product in Reference	Linezolid 100 mg/5 ml granules for oral suspension by

	Regulatory Authorities.	Pfizer.(PL 00057/1420) Approved in MHRA
	Me-too status	Nezolid 100mg Suspension of Searle Pak, Karachi (Reg. # 050326)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Oral Powder suspension (General) section
	Remarks of the Evaluator.	
	Decision: Approved.	
1842.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultazole 50mg / 5ml Suspension
	Composition	Each ml contains: Fluconazole……..10mg
	Diary No. Date of R& I & fee	14927, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	30ml; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Zefung Dry Powder Suspension of Nexus Pharma
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Fee challan does not specify brand name, strength and dosage form of applied product. Only API is written as "Fluconazole". Label claim and master formulation does not suggest Dry powder suspension. Revision of Form-5 is required.
	Decision: Deferred for revision of formulation as per reference product alongwith submission of applicable fee.	
1843.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	CLARTON 125mg /5ml Dry Suspension
	Composition	Each 5ml contains: Clarithromycin taste masked granules 27.5% eq. to Clarithromycin……..125mg / 5ml
	Diary No. Date of R& I & fee	16530, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	60ml; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Biaxin granules for oral suspension 125mg/5mlbyM/s Abbvie, USFDA approved.
	Me-too status	Klarim Dry Suspension 125mg/5ml of Amrose Pharma
	GMP status	As recoded for above application
	Remarks of the Evaluator.	Brand name mentioned on Fee challan Clartex 125mg / 5ml while that mentioned on Form-5 is Clarton 125mg / 5ml. Clarification is required. Source of granules is required to be submitted.
	Decision: Deferred for clarification of brand name on fee challan and submission of source of clarithromycin granules.	
1844.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Azithromycin 250mg Dry Suspension
	Composition	Each 5ml contains: Azithromycin ……..250mg

	Diary No. Date of R& I & fee	14926, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	60ml; As recommended by PRC
	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	As recoded for above application
	Remarks of the Evaluator.	You have applied Azithromycin 250mg Dry Suspension while reference formulation is 200mg Dry Suspension. Clarification / Revision of Form-5 with requisite fee is required.
	Decision: Deferred for revision of formulation as per reference product alongwith requisite fee.	
Sachet (General) Section (1molecule/ 1product)		
1845.	**Name and address of manufacturer / Applicant**	**M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar**
	Brand Name +Dosage Form + Strength	Athanpartate 3gm Oral Granules
	Composition	Each 5g Oral Granules contains: L-ornithine Aspartate……3gm
	Diary No. Date of R& I & fee	14919, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Hepatoprotective, Lipotropic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	5g Sachet × 5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Austria
	Me-too status	Hepaser Sachet 3gm of M/s Panacea Pharma (Reg#075403)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

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

a. New section

Liquid Injectable (Hormone) Section: (5molecules/12 products)		
1846.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	BUSALIN INJECTION
	Composition	Each ml contains: Buserelin Acetate……0.0042mg eq. to 0.004mg of Buserelin
	Diary No. Date of R& I & fee	40597, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Gonadotropin-releasing hormone agonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 10's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Conceptal Injection of M/s STAR LAB (Reg#058939)
	GMP status	CLB in its 266th meeting held on 24th October, 2018 has considered and approved the following additional section. Liquid Injectable (Hormone) Section (DML# 000747).
	Remarks of the Evaluator.	Follix Injection is mentioned on fee challan. Clarification is required.
	Decision: Deferred for following: **Clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.**	

	Clarification of applied product on fee challan.	
1847.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	BUSALIN INJECTION
	Composition	Each ml contains: Buserelin Acetate……0.0042mg eq. to 0.004mg of Buserelin
	Diary No. Date of R& I & fee	40599, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Gonadotropin-releasing hormone agonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5ml × 10's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Conceptal injection of M/s STAR LAB (Reg#058939)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1848.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	BUSALIN INJECTION
	Composition	Each ml contains: Buserelin Acetate…0.0042mg eq. to 0.004mg of Buserelin
	Diary No. Date of R& I & fee	40600, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Gonadotropin-releasing hormone agonist
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2.5ml × 10's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Conceptal injection of M/s STAR LAB (Reg#058939)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1849.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	FOLLIX INJECTION
	Composition	Each ml contains: Estradiol dipropionate……..1.00mg
	Diary No. Date of R& I & fee	40596, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Estrogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Agofollin injection of Ghazi Brothers (Reg#028587)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1850.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	FOLLIX INJECTION

	Composition	Each ml contains: Estradiol dipropionate……..1.00mg
	Diary No. Date of R& I & fee	40594, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Estrogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 5's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Agofollin injection of Ghazi Brothers (Reg#028587)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1851.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	DROSTEN INJECTION
	Composition	Each ml contains: D-Cloprostenol……..0.75mg
	Diary No. Date of R& I & fee	40587, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 1's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Delmazine Injectable solution of M/s Prix Pharmaceutica (Reg#018842)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	The submitted me-too reference is of different strength i.e.,D-Cloprostenol…….0.075 mg per ml.
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1852.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	DROSTEN INJECTION
	Composition	Each ml contains: D-Cloprostenol……..0.75mg
	Diary No. Date of R& I & fee	40595, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 10's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Delmazine Injectable solution of Prix Pharma (R#018842)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	The submitted me-too reference is of different strength i.e.,D-Cloprostenol…….0.075 mg per ml.
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1853.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	DROSTEN INJECTION
	Composition	Each ml contains: D-Cloprostenol……..0.75mg

	Diary No. Date of R& I & fee	40593, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Prostaglandin analogue
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 1's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Delmazine Injectable solution of M/s Prix Pharmaceutica (Reg#018842)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	The submitted me-too reference is of different strength i.e.,D-Cloprostenol……0.075 mg per ml.
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1854.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	MYRALIN INJECTION
	Composition	Each ml contains: Lecirelin……25mcg
	Diary No. Date of R& I & fee	40588, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic superanalogue of GnRH (gonadotropin releasing hormone)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 10's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	SERILIN Injection of M/s Selmore Pharma (Reg#071092)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1855.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	MYRALIN INJECTION
	Composition	Each ml contains: Lecirelin……25mcg
	Diary No. Date of R& I & fee	40588, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic superanalogue of GnRH (gonadotropin releasing hormone)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2ml × 5's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	SERILIN Injection of M/s Selmore Pharma (Reg#071092)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1856.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	MYRALIN INJECTION
	Composition	Each ml contains: Lecirelin……25mcg
	Diary No. Date of R& I & fee	40591, 06-12-2018, 20,000/-, 04-12-2018

	Pharmacological Group	Synthetic superanalogue of GnRH (gonadotropin releasing hormone)
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5ml × 5's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	SERILIN Injection of M/s Selmore Pharma (Reg#071092)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	
1857.	Name and address of manufacturer / Applicant	M/s Mylab PVT. LTD., Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	STYROL INJECTION
	Composition	Each ml contains: Stilbestrol Dipropionate……10mg
	Diary No. Date of R& I & fee	40589, 06-12-2018, 20,000/-, 04-12-2018
	Pharmacological Group	Synthetic Estrogen
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10ml × 10's clear glass vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	BESTEROL Injection of M/s Selmore (Reg#071085)
	GMP status	As recoded for above application
	Remarks of the Evaluator.	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	

Case No. 05: Registration Applications of Import Cases:

a. Deferred cases

i. Human

1858.	Name and address of Applicant	M/s. Mehran Dental, Karachi. M No. Al Noor Centre Randle Road, ADJANKLE Seria Hospital, Karachi
	Details of Drug Sale License	
	Name and address of manufacturer	M/s. Laboratorios zeyco s.a. De c.v. Camino a santa ana tepetitlan no. 2230 colonia santa ana tepetitlan 45230 zapopan jalisco, Mexico.
	Name and address of marketing authorization holder	-do-
	Name of exporting country	Mexico
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Diary No.153 Dated 17-02-2009
	Fee including differential fee	Rs.15000/- (18-06-2013) + Rs.85000/-
	Brand Name +Dosage Form + Strength	FD Injection IV
	Composition	Each 1.8ml ampoule contains: - Lidocaine HCl……36.0mg Epinephrine…….0.018mg
	Pharmacological Group	Local Anesthetic/Adrenergic agonist
	Finished Product Specification	In House
	Shelf life	---------
	Pack size	1 x 10 cartridge ineach blister Total 5 blisterin packet Total 50 pieces of cartridges in Packet
	Demanded price	Rs. 1200/-

	International availability	Lidocaine and Epinephrine By Hospira, USFDA
	Me-too status	Rapicaine by S.Ejazuddin (imported)
	Detail of certificates attached	
	Previous Remarks of the Evaluator.	Sole agency agreement has been expired. GMP certificate of manufacturer has been expired. Firm has not provided original & legalized Certificate of Pharmaceutical Product with English translation. Firm has not provided long term stability studies under zone IV-A conditions are ICH/WHO guidelines. Chromatograms in analytical methods & stability studies have not been provided along with data. Firm gave reference of USP for finished product specifications while given assay method is not as same as given in USP 35. Firm has not provided active raw material specifications. Firm has not provided specifications of primary packaging material (glass vial). Undertaking on desired format has not been submitted.
	Previous Decisions	**Registration Board deferred the case for rectification of following observations in the dossier: (M-246)** a. Sole agency agreement has been expired. b. GMP certificate of manufacturer has been expired. c. Firm has not provided original & legalized Certificate of Pharmaceutical Product with English translation. d. Firm has not provided long term stability studies under zone IV- A conditions are ICH/WHO guidelines. e. Chromatograms in analytical methods & stability studies have not been provided along with data. f. Firm gave reference of USP for finished product specifications while given assay method is not as same as given in USP 35. g. Firm has not provided active raw material specifications. h. Firm has not provided specifications of primary packaging material (glass vial). g. Undertaking on desired format has not been submitted. **Registration Board deferred the case for the following reasons (M-270)** • Only long term stability studies have been submitted while the assay of all 3 batches of epinephrine shows a significant change that is difference in the assay values is more than 5% from its initial value. • Following documents are not submitted: Sole agency agreement Original legalized CoPP GMP certificate Undertaking as per requirement of Form-5(A).
	Evaluation by PEC	1. The product is available in USP as injection but the firm has claimed In-House specifications. 2. Specifications for primary packaging material have been provided. • The firm has submitted justification for significant change in assay values of epinephrine as follows: "This requirement is mostly impossible to meet for any dental cartridge manufacturer in the world given the physicochemical properties of epinephrine. Our product FD is manufactured with a 15% overage of epinephrine in order to counter epinephrine fast degradation occurring from the solution

		preparation until the manufacturing process is completed. The USP monograph specifies that the solution should contain the equivalent of not less than 90.0% and not more than 115.0% of the labeled amount of Epinephrine. The unusual limits are due to high degradation losses of epinephrine occurring during the manufacturing process prior to the FPP release. Once the solution is packed inside the cartridges, the degradation becomes slower as the epinephrine stabilizes inside its container. The purpose of the overage is not to extend the shelf life of the product; instead, it is a part of the manufacturing process in order to obtain a product for release with an epinephrine assay within USP specifications near to 100% according to labeled amount." • Regarding CoPP, the firm has submitted that "*The certificate of pharmaceutical product is not legally defined in Mexico, however, the legislation issues currently its equivalent document which is a free sale certificate (FSC) for health inputs which includes all information contained in a Certificate of Pharmaceutical Product.*" • Original Legalized free sale certificate issued by Ministry Of Health, Federal commission for the protection against Health Risks, Mexico Issued on: 15-01-2019 • Original, legalized Declaration letter dated 01-02-2019 from **M/s. Laboratorios Zeyco s.a. de C.V. Camino a santa ana tepetitlan no. 2230 colonia santa ana tepetitlan 45230 zapopan jalisco, Mexico** do hereby declare to export to the territory of the Islamic Republic of Pakistan through our distributor Mehran Dental Supplier. • Copy of GMP certificate of the manufacturer is submitted which is issued on 31-07-2017. Certificate No: 173300516A0786. Valid till April, 2019. • ***Valid Legalized copy of GMP certificate is required.***
	Decision: Deferred for following: • **Submission of original, valid legalized GMP certificate** • **Submission of details of drug sale license.**	

Case No. 07: Registration Applications of Drugs for Which Stability Study Data is Submitted.

a. Deferred cases

1859.	Name and address of manufacturer / Applicant	M/s Seraph Pharmaceutical Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Serbica 20mg capsule
	Composition	Each capsule contains; Isotretinoin…….20mg
	Diary No. Date of R& I & fee	08-06-2017 / Dy No. 5155 / Rs.20,000/-
	Pharmacological Group	AntiAcne
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	30's, 20's, 10's, 5's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Absorica 20mg capsule by Ranbaxy Laboratories (USFDA Approved)
	Me-too status	Atractin by Genome
	GMP status	New License (Inspection Date: 8th May 2017)

	Remarks of the Evaluator	
	Decision of previous meeting:	• Deferred for confirmation of manufacturing process/facility for applied formulation/dosage form as decided by Registration Board for this product (M-271) • Deferred for clarification of submitted manufacturing method for applied formulation particularly how nitrogen purging will be carried out during manufacturing of hard gelatin capsules and justification in light of decision of 250th meeting (M-275)
	Evaluation by PEC:	• Firm has replied that they have applied as per the formulation and specification of Absorbica capsule in hard gelatin which is formulated with appropriate oleaginous vehicles for stability and efficient antioxidants to prevent the product from oxidation. • The filling of capsules will be carried out by semi-automatic capsule filling machine and after filling empty capsule shells in dyes, the cap and body of shells will be seprated and the body will be nitrogen purged by nozzles of cylinders containing nitrogen. After purging the material will be immediately filled in body of capsule shells and capsule will be locked immediately to minimize the air contact. • The formulation as per annovator containing oleaginous vehicles and antioxidants itself is sufficient for stability of product and that the nitrogen purging is an additional precautionary step for product stability.
	Decision of previous meeting:	The Board deferred the case for further evaluation. (M-277)
	Remarks of Evaluator: The firm has submitted that the product was formulated with appropriate oleaginous vehicles for stability and with efficient antioxidants in order to prevent the product from oxidation. To ensure this firm has conducted accelerated and real time stability study data and submitted it along with required documents as per checklist approved in 251st meeting of Registration Board. Detailsof submitted data are as under: (Dy.# 31426 dated 18-09-2018)	

STABILITY STUDY DATA

Drug	Serbica 20mg capsule		
Name of Manufacturer	M/s Seraph Pharmaceutical Plot No. 210, Industrial Triangle, Kahuta Road, Islamabad		
Manufacturer of API	Shanghai New Hualian Pharmaceutical Co. Ltd. No.217, Minle Road, Spark Zone, Haiwan Town, Fengxian District Shanghai.		
API Lot No.	C014-171106		
Description of Pack (Container closure system)	3x10's: Alu-Alu blister packed in cardboard unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months		Accelerated: 6 months
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months)		Real Time: 0, 3, 6 (Months)
Batch No.	T-001	T-002	T-003
Batch Size	500 capsule	500 capsule	500 capsule
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	16-02-2018	21-02-2018	23-02-2018

No. of Batches	03	
Date of Submission	(Dy.# 31426 dated 18-09-2018)	
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.	Firm has submitted GMP certificate (No. SH20150008) issued by state Food and Drug Administration 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.	Firm has submitted copy of Packing list, invoice, Form 7, Form 3, COA and DHL invoice for import of 50g Isotretinoin on 26-01-2018from Shanghai New Hualian Pharmaceutical through Kimwell Pharma Limited.
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 used BP method for testing of the finished product which is based on analytical methods of UV spectroscopy, furthermore the BP monograph is for isotretinoin soft gelatin capsule.

Report on investigation of genuineness / authenticity of data submitted for registration of SERBICA Capsule 20mg (Isotretinoin Hard Gelatin Capsule 20mg) by M/s Seraph Pharmaceutical, Islamabad.
Reference No: F.13-11/2017-PEC (Pt) dated 29th October, 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. in addition to verify and report about the following point for consideration of Registration Board:

. Firm has used BP method for testing of the finished product which is based on analytical methods of UV spectroscopy. Furthermore, the BP monograph is for isotretinoin soft gelatin capsule.

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:

Q. No.	Question	Observation by Panel
1.	Do you have documents confirming the import API including approval from DRAP?	Firm have shown copy of DHL invoice for import of 50g Isotretinoin on 26-01-2018 from Shanghai New Hualian Pharmaceutical through Kimwell Pharma limited.
2.	What was the rationale behind selecting the particular manufacturer of API?	Firm informed that they have selected API's supplier on the basis of GMP Certification & CEP Certification for Isotretinoin from EDQM (R1-CEP 2008-231-Rev 01) and Vendor Prequalification (Desktop).
3.	Do you have documents confirming the import of API reference standard and impurity standards?	The firm had analyzed using Reference Absorbance value of Standard given in BP Monograph.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Firm have Certificate of Analysis of the API (Batch No. C014-171106).
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm have copy of GMP certificate No. SH20150008 of M/s Shanghai New Hualian Pharmaceutical Co., Ltd., China issued by State Food and Drug Administration, China.
6.	Do you use API manufacturer method of testing for testing API?	Firm have used BP Method for testing of API (Isotretinoin) whereas the API Manufacturer have used USP-36 Monograph.
7.	Do you have stability studies reports on API?	Firm have shown copy of 06 Months (Accelerated) and 36 Months (Real Time) Stability Study Reports on 03 Batches of API (Isotretinoin) conducted by the API Manufacturer.
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.
9.	Do you have method for quantifying the impurities in the API?	Firm have 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 have 15 gm of the API (Isotretinoin) remaining.
11.	Have you used pharmaceutical grade excipients?	Firm have used pharmaceutical grade excipients: • Avicel 102 • Stearoyl polyoxyl glyceride • Soybean oil • Tween 80 • Propyl gallate
12.	Do you have documents confirming the import of the used excipients?	Firm has shown documents confirming the import of the used excipient (Avicel 102); others were purchased locally.
13.	Do you have test reports and other records on the excipients used?	Firm have test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of applied product?	Firm have shown a generalized protocol for the development of new products. Firm was advised to adopt SOP for Product Specific New Product Development Protocol.
15.	Have you performed Drug-excipients compatibility studies?	Firm have not performed Drug-excipients compatibility studies and claims to use same excipients as that of Innovator (ABSORICA™).
16.	Have you performed comparative dissolution studies?	Firm have performed comparative study of their product with ABSORICA™ Hard Gelatin Capsule 20mg. Details are as follows:

		<table><tr><td>Details</td><td>Test Product</td><td>Reference Product</td></tr><tr><td>Brand</td><td>SERBICA</td><td>ABSORICA™</td></tr><tr><td>Batch No.</td><td>T001</td><td>10-3243</td></tr><tr><td>Mfg. Date</td><td>2/2018</td><td>2/2018</td></tr><tr><td>Medium</td><td>900ml of 0.1M of NaOH at 37°C.</td><td>900ml of 0.1M of NaOH at 37°C.</td></tr><tr><td colspan="3">Remarks: The analysis was performed using BP Method for Dissolution Testing in DT apparatus.</td></tr></table> Test product showed comparable results with the reference product.
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 capsule filling was done in Production area using Semi-automatic Capsule Filling Machine tailored with nozzles of cylinders containing Nitrogen for purging.
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 02-2018 for the stability studies of applied product having batch size of 500 capsules 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 used BP Method and conducted Analytical Method Verification using 04 parameters.
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?	Firm have used BP Method for testing of FPP however Impurity profiling was not performed.
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. Stability batches are kept on Real Time Stability Testing.
33.	Do you have stability batches kept on	Firm have stability batches kept on Real Time Stability

	stability testing?	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. 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.
37.	To verify and report about the following point for consideration of Registration Board: ~Firm has used BP method for testing of the finished product which is based on analytical methods of UV spectroscopy. Furthermore, the BP monograph is for isotretinoin soft gelatin capsule.	The panel verifies that the Firm has used BP method for testing of the finished product which is based on analytical methods of UV spectroscopy. Moreover, the BP Monograph does not specify whether it can only be used for isotretinoin soft gelatin capsule. Submitted for consideration of Registration Board.

CONCLUSION:

On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of SERBICA Capsule 20mg (Isotretinoin Hard Gelatin Capsule 20mg) is verifiable to satisfactory level.

Previous Decision: Registration Board deliberated that since applied formulation is prone to oxidation, and is likely to undergo degradation, hence 6 months stability data could not be considered sufficient to ascertain shelf life of 2 years. Therefore Registration Board directed the firm to submit Long term stability studies data for one year. Moreover Board directed the firm to justify the use of UV spectroscopy instead of HPLC for Assay analysis of applied formulation **(M-287).**

Evaluation by PEC: The firm has submitted that rationale behind the use of UV method is that;

As we are using the testing method defined in British Pharmacopoeia and the method given in British Pharmacopoeia for the analysis of capsule is UV method. Hence we have tested the product as per British Pharmacopoeia monograph.

The firm has submitted real time stability study data of 9^{th} and 12^{th} month time points of three trial batches.

Decision: Registration Board deferred the case for provision of real time stability data upto assigned shelf life.

a. Exemption from onsite verification of stability data

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 GMP Inspection Report Date Remarks
1860.	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Tikanox-60 Tablets Each Film coated tablet contains: Ticagrelor……60mg Platelet activation inhibitor Manufacturer's specifications	Form 5-D Dairy No.1984 dated 25-05-2016, Rs.50,000/-, 24-05-2016, Not mentioned	Brilinta Tablet of Astrazeneca Pharms **(USFDA approved)** **N/A** 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 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 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: 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. **Date of inspection**: 8th August, 2018 The HPLC software of the firm is 21 CRF compliant. 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 (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.
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.	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.
5.	Mechanism for Vendor pre-qualification	The firm has submitted Mechanism for Vendor pre-qualification.

<table>
<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.
• Copy of COA of working standards have been submitted
• COAs of impurity standards have been submitted.
Impurity A
Impurity B
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>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>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated (40^{o}C±2^{o}C/75%±5%RH) and 36 Months Real Time (25^{o}C±2^{o}C/60%±5%RH) Stability Study Data of 03 Batches for Ticagrelor from M/s Glenmark Pharmaceuticals 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>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that ingredients of Tikanox-60 Tablets and Brilinta 60mg Tablet (innovator brand) are</td></tr>
</table>

		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.

Previous Decision: Registration Board deferred the case for submission of stability data of API from supplier conducted at Zone IV-A conditions and submission of comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8 **(M-288)**.

Evaluation by PEC:

The firm has submitted long term stability data of three batches of API conducted at Zone IV-A.

The firm has performed comparative dissolution studies conducted at pH 1.2, pH 4.5, pH 6.8 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 90mg Tablets.

Decision: Registration Board deferred the case for confirmation of polymorphic form of API Ticagrelor.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date Remarks
1	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Tikanox-90 Tablets Each Film coated tablet contains: Ticagrelor……90mg Platelet activation inhibitor Manufacturer's specifications	Form 5-D Dairy No.1985 dated 25-05-2016, Rs.50,000/-, 24-05-2016, Not mentioned	Brilinta Tablet of Astrazeneca Pharms **(USFDA approved)** **N/A** 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 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: 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. **Date of inspection**: 8th August, 2018 The HPLC software of the firm is 21 CRF compliant.

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<tr><td></td><td></td><td>The firm has provided USB data loggers, which are set for recording temperature and humidity after each hour.</td></tr>
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<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:
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<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>
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<tr><td>T-002</td><td>878</td><td>244</td></tr>
<tr><td>T-003</td><td>870</td><td>236</td></tr>
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<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</td></tr>
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		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 ($40^{o}C \pm 2^{o}C/75\% \pm 5\%RH$) and 36 Months Real Time ($25^{o}C \pm 2^{o}C/60\% \pm 5\%RH$) 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.		

Previous Decision: Registration Board deferred the case for submission of stability data of API from supplier conducted at Zone IV-A conditions and submission of comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8 **(M-288)**.

Evaluation by PEC:

The firm has submitted long term stability data of three batches of API conducted at Zone IV-A.

The firm has performed comparative dissolution studies conducted at pH 1.2, pH 4.5, pH 6.8 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.

Decision: Registration Board deferred the case for confirmation of polymorphic form of API Ticagrelor.

MISCELLENEOUS CASES:

REGISTRATION-I

Case No.1. Request For Change in Registration Status of Products From M/s AGP Ltd, Karachi To M/s. Aspin Pharma, Karachi.

Registration Board in its 288th meeting considered the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 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 Each tablet contains: Rosuvastatin as calcium ….5mg (Manufacturer Specifications)	Rs. 120.00/ 10's	Initial date of Reg. 02-03-2009 Last Renewal 02-03-2014	Dy.No.3395 11-02-2019 Rs.70,000/- Standard Formulation approved by RRAs is film coated.
2	055122	Xovat 10mg Tablet Each tablet contains: Rosuvastatin as calcium ….10mg (Manufacturer Specifications)	Rs. 200.00/ 10's	Initial date of Reg. 02-03-2009 Last Renewal 02-03-2014	Dy.No.3396 11-02-2019 Rs.70,000/- Standard Formulation approved by RRAs is film coated.
3	055123	Xovat 20mg Tablet Each tablet contains: Rosuvastatin as calcium ….20mg (Manufacturer Specifications)	Rs. 400.00/ 10's	Initial date of Reg. 02-03-2009 Last Renewal 02-03-2014	Dy.No.3397 11-02-2019 Rs.70,000/- Standard Formulation approved by RRAs is film coated.
4	082244	Xovat 40mg Tablet Each tablet contains: Rosuvastatin as calcium….20mg (As per Innovators Specifications)	Rs. 800.00/ 10's	Initial date of Reg. 26-09-2017	Dy.No.3398 11-02-2019 Rs.70,000/- 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 of M-288:

Registration Board decided as follows:

i. Cancellation of registration of products at S.No. 1-4from 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).*

Furthermore, M/s Aspin, Karachi has 04 approved sections, therefore, entitled to contract manufacturing of 20 products as per policy of 5 products per section.

Now the firm has submitted a request stating that:

"Due to restriction of maximum 20 contract manufacturing of products as per contract manufacturing policy, we here by request your good office to withdraw the above mentioned products for transfer of registration via contract manufacturing and consider these applications null and void"

Decision: **Registration Board acceded to the request of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for withdrawal of their previously submitted application regarding change in registration status of above mentioned products via contract manufacturing. Decision taken in 288th meeting shall stand *void ab initio.***

Case No.2. Request for Change in Registration Status of Products From M/s OBS Pakistan (Pvt.) Ltd, Karachi To M/s. Aspin Pharma, Karachi.

Registration Board in its 288th meeting considered the request of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 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 Each capsule contains: Pregabalin .... 25mg (As per Innovator's Specifications)	Rs.121.00/ 14's	Initial date of Reg. 31-12-2018	Dy.No.3393 08-02-2019 Rs.70,000/-
2	093006	Gabolest Capsule 50mg Each capsule contains: Pregabalin ... 50mg (As per Innovator's Specifications)	Rs.202.00/ 14's	Initial date of Reg. 31-12-2018	Dy.No.3392 08-02-2019 Rs.70,000/-
3	093007	Gabolest Capsule 100mg Each capsule contains: Pregabalin .... 100mg (As per Innovator's Specifications)	Rs.281.00/ 14's	Initial date of Reg. 31-12-2018	Dy.No.3390 08-02-2019 Rs.70,000/-
4	093008	Gabolest Capsule 200mg Each capsule contains: Pregabalin .... 200mg (As per Innovator's Specifications)	Rs.468.00/ 14's	Initial date of Reg. 31-12-2018	Dy.No.3388 08-02-2019 Rs.70,000/-
5	093009	Gabolest Capsule 225mg Each capsule contains: Pregabalin .... 225mg (As per Innovator's Specifications)	Rs.526.00/ 14's	Initial date of Reg. 31-12-2018	Dy.No.3387 08-02-2019 Rs.70,000/-
6	076661	Gabolest Capsule 150mg Each capsule contains: Pregabalin ..... 150mg (As per Innovator's Specifications)	Rs.815.00/ 14's	Initial date of Reg. 23-01-2015	Dy.No.3389 08-02-2019 Rs.70,000/-

7	076662	Gabolest Capsule 300mg Each capsule contains: Pregabalin ..... 300mg (As per Innovator's Specifications)	Rs.1358.00/ 14's	Initial date of Reg. 23-01-2015	Dy.No.3386 08-02-2019 Rs.70,000/-
8	076663	Gabolest Capsule 75mg Each capsule contains: Pregabalin .... 75mg (As per Innovator's Specifications)	Rs.490.00/ 14's	Initial date of Reg. 23-01-2015	Dy.No.3391 08-02-2019 Rs.70,000/-
9	089147	Kapdex 30mg Capsule Each capsule contains: Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole…30mg (As per Innovator's Specification)	Rs.451.00/ 30's	Initial date of Reg. 31-05-2018	Dy.No.3383 08-02-2019 Rs.70,000/- Pellets registered source: M/s Vision Pharmaceuticals, Islamabad
10	089148	Kapdex 60mg Capsule Each capsule contains: Dexlansoprazole dual delayed release pellets eq. to Dexlansoprazole..60mg (As per Innovator's Specification)	Rs.696.00/ 30's	Initial date of Reg. 31-05-2018	Dy.No.3382 08-02-2019 Rs.70,000/- Pellets registered source: M/s Vision Pharmaceuticals, Islamabad
11	075821	Virunix-B 1mg Tablet Each film coated tablet contains: Entecavir as monohydrate ...1mg (Manufacturer Specifications)	Rs. 17000.00/ 30's	Initial date of Reg. 03-04-2013 Renewal 18-01-2018	Dy.No.3384 08-02-2019 Rs.70,000/- USP Monograph is available for applied formulation
12	075822	Virunix-B 0.5mg Tablet Each film coated tablet contains: Entecavir as monohydrate...0.5mg (Manufacturer Specifications)	Rs. 9000.00/ 30's	Initial date of Reg. 03-04-2013 Renewal 18-01-2018	Dy.No.3385 08-02-2019 Rs.70,000/- 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 of M-288:

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).*

Now the firm has submitted a request stating that:

"Due to restriction of maximum 20 contract manufacturing of products as per contract manufacturing policy, we here by request your good office to withdraw our previous applications and consider above mentioned products for complete Marketing authorization/ Registration transfer of products from OBS Pakistan Pvt. Ltd to M/s Aspin Pharma Pvt. Ltd. located at Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900. Pakistan. (Dy.No.265 to 276/DDC (Reg-I) dated 17-04-2019)

The firm has also submitted fresh fee of Rs.20,000/- each for product at Sr.No.09-10 (Dy.No 419 & 420/DDC(Reg-I) dated 03-05-2019)(Source of pellets: M/s Vision Pharma, Islamabad)

Decision: **Registration Board acceded to the request of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 and decided as follows:**

i. **Cancellation of registration of products at S.No. 1-8 & 11-12from the name of M/s. OBS Pakistan (Pvt.) Ltd; C-14, S.I.T.E, Karachi.**
ii. **Approved registration of products at S.No. 1-8 & 11-12in the name of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900.**
iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**
iv. **Deferred the request w.r.t products at S.No.9-10 for submission of stability data& associated documents.**
v. **Decision taken in 288th meeting shall stand *void ab initio.***

Case No.03: Request of M/s. Aspin Pharma, Karachi for Change in Registration Status of Products of M/s. OBS Pakistan (Pvt) Ltd, Karachi.

Registration Board, in its 287th meeting held on 03-04th January,2019, deferred the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No.10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for change of registration status of following product from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name**for submission of source of Mebeverine extended release pellets, by the firm.**Details are given as under:

S.No.	Name of Drug(s) with composition	Reg.No.	Approved Pack/ MRP	Registration History	Remarks
I	II	III	IV	V	VI
1.	Bever-M 200mg Capsule Each capsule contains:	084748	Rs.142/10's	Initial date of Reg.	Documents related to source of pellets

	Mebeverine HCI as extended release pellets eq. to Mebeverine HCl .....200mg (Innovator's Specification) **Source:** M/s RA Chem Pharma Ltd, India			09-08-2017	along with differential fee of Rs.80,000 are yet to be provided.

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 approval of M/s Aspin verified from Licensing Division's letter for renewal of DML (dated 09th June, 2016) confirming following sections;
   - Tablet (General)
   - Capsule (General)
   - Liquid Syrup
   - Ointment/ Cream.
iv. Copy of last GMP inspection report of M/s Aspin, Karachi dated 08th August, 2018 indicating "Satisfactory" level.
v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 19th November, 2018.
vi. DML of M/s Aspin dated 31st May, 2015.

The firm has now submitted requisite documents (Copy of GMP, COA and stability Studies)for source of Mebeverine Pellets from M/s RA Chem Pharma Ltd. India along with fee of Rs.100,000/-(Dy.135/DD(R-I) dated 19-Mar-19)

Decision: Registration Board decided as follows:

i. Cancellation of registration of Bever-M 200mg Capsule (R#084748) from the name of M/s. OBS Pakistan (Pvt.) Ltd; C-14, S.I.T.E, Karachi.

ii. Approved registration of Bever-M 200mg Capsule in the name of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900.

iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP). Furthermore, Registration certificate shall be issued after submission of valid & legalized GMP certificate of M/s RA Chem Pharma Ltd. India.

Case No.4. Request for Change in Registration Status of Products from M/s OBS Pakistan (Pvt.) Ltd, Karachi to M/s. Aspin Pharma, Karachi.

Registration Board in its 288th meeting considered the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 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 Each 5ml contains: Cefixime as trihydrate...100mg (USP Specifications)	Rs.180.00/ 30ml	Initial date of Reg. 30-07-2009 via contract Manufacturing from M/s Mediate Pharma Ltd	Dy.No.3414 11-02-2019 Rs.20,000/-

2	057943	M-Span 200mg/5ml Dry Suspension Each 5ml contains: Cefixime as trihydrate...200mg (USP Specifications)	Rs.300.00/ 30ml	Change of Contract Manufacturing to M/s Macter International 07-02-2011 Change of Contract Manufacturing to M/s AGP Ltd 14-12-2015 Permission is valid up to 30-06-2020	Dy.No.3416 11-02-2019 Rs.20,000/-
3	057944	M-Span 400mg Capsules Each capsule contains: Cefixime as trihydrate...400mg (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 29th January, 2019.
vi. Consent/NOC from M/s. AGP Limited, D-109, S.I.T.E, Karachi dated 29th January, 2019 for Contract manufacturing of above mentioned products.
vii. DML of M/s Aspin dated 31st 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 of M-288: *Registration Board deferred the request for submission of requisite fee for grant of contract manufacturing permission.*

The firm has now submitted differential fee of Rs.50,000/- for each product (Dy.No.1164/ (R&I) dated 19-Mar-19).

Decision: Registration Board decided as follows:

i. Cancellation of registration of products at S.No. 1-3from the name of M/s. OBS Pakistan (Pvt.) Ltd; C-14, S.I.T.E, Karachi.
ii. Approved registration of products at S.No. 1-3in 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 Limited, D-109, S.I.T.E, Karachi.
iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).

Case No.5. Request For Change in Registration Status of Products From M/s OBS Pakistan (Pvt.) Ltd, Karachi To M/s. Aspin Pharma, Karachi.

Registration Board in its 288th meeting considered the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 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 Each vial contains: Imipenem Monohydrate	Rs.776.55/1's	Date of Reg. in the name of M/s OBS Pakistan (Pvt) Ltd,	Dy.No.3399 11-02-2019 Rs.20,000/-

		eq. to Imipenem ….500mg Cilastatin Sodium eq. to Cilastatin …. 500mg (USP Specifications)		Karachi via contract Manufacturing from M/s Global Pharmaceuticals Pvt. Ltd: 29-12-2018	

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 of M-288: *Registration Board deferred the request for submission of requisite fee for grant of contract manufacturing permission.*

The firm has now submitted differential fee of Rs.50,000/- (Dy.No.1165/ (R&I) dated 19-Mar-19)

Decision: Registration Board decided as follows:

i. **Cancellation of registration of Onem IV Injection (R# 089308) from the name of M/s. OBS Pakistan (Pvt.) Ltd, C-14, S.I.T.E, Karachi.**
ii. **Approved registration of Onem IV Injection 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. Global Pharmaceuticals Pvt. Ltd, Islamabad.**
iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

Case No.6. 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. The details are given as under:

I	II	III	IV	V
S.No.	**Name of Drug(s)**	**Reg.No.**	**Registration History**	**Remarks**
1.	Obsarib Capsule Each capsule contains: Ribavirin .....400mg (Manufacturer's specification)	075820	Initial date of Reg. 03-04-2013 Last Renewal 18-01-2018	Dy.No7412 (R&I) 20-02-2019 Rs.20,000/- Duplicate Dossier
2.	Obsarib Tablet Each film coated tablet contains: Ribavirin .....600mg (Manufacturer's specification)	081468	Initial date of Reg. 03-08-2016	Dy.No7414 (R&I) 20-02-2019 Rs.20,000/- Duplicate Dossier
3.	Obsarib Tablet Each film coated tablet contains: Ribavirin .....500mg (Manufacturer's specification)	081469	Initial date of Reg. 03-08-2016	Dy.No7413 (R&I) 20-02-2019 Rs.20,000/- Duplicate Dossier

4.	Fitzloc 250mg Tablet Each film coated tablet contains: Levetiracetam .....250mg (Manufacturer's specification)	076293	Initial date of Reg. 21-04-2014 Last Renewal 22-02-2019 with fee of Rs.10,000/-	Dy.No.3309 (R&I) 11-04.2019 Rs.20,000/-
5.	Fitzloc 500mg Tablet Each film coated tablet contains: Levetiracetam .....500mg (Manufacturer's specification)	076294	Initial date of Reg. 21-04-2014 Last Renewal 22-02-2019 with fee of Rs.10,000/-	Dy.No.3310 (R&I) 11-04.2019 Rs.20,000/-
6.	Fitzloc 750mg Tablet Each film coated tablet contains: Levetiracetam .....750mg (Manufacturer's specification)	076295	Initial date of Reg. 21-04-2014 Last Renewal 22-02-2019 with fee of Rs.10,000/-	Dy.No.3311 (R&I) 11-04.2019 Rs.20,000/-
7.	C-Yalta 20mg Capsule Each capsule contains: Duloxetine HCl enteric coated pellets eq. to Duloxetine … 20mg (Manufacturer's Specifications)	076116	Initial date of Reg. 25-10-2013 (Source of Pellets: M/s Spansules formulation , India) Last Renewal applied on 27-09-2018 With fee of Rs.10,000/-Pellets are being imported from India and the firm has submitted renewal fee of Rs.10,000/- only	Dy.No.3318 (R&I) 11-04.2019 Rs.20,000/- Dy.No.4923 (R&I) 30-04.2019 Rs.100,000/- *Applied Source of Pellets:* *M/s Spansules, India*
8.	C-Yalta 60mg Capsule Each capsule contains: Duloxetine HCl enteric coated pellets eq. to Duloxetine … 60mg (Manufacturer's Specifications)	076117	Initial date of Reg. 25-10-2013 (Source of Pellets: M/s Spansules formulation , India) Last Renewal applied on 27-09-2018 With fee of Rs.10,000/-Pellets are being imported from India and the firm has submitted renewal fee of Rs.10,000/- only	Dy.No.3320 (R&I) 11-04.2019 Rs.20,000/- Dy.No.4941(R&I) 30-04.2019 Rs.100,000/- *Applied Source of Pellets:* *M/s Spansules, India*
9.	C-Yalta 30mg Capsule Each capsule contains: Duloxetine HCl enteric coated pellets eq. to Duloxetine … 30mg (Manufacturer's Specifications)	076118	Initial date of Reg. 25-10-2013 (Source of Pellets: M/s Spansules formulation , India) Last Renewal applied on 27-09-2018 With fee of Rs.10,000/-Pellets are being imported from India and the firm has submitted renewal fee of Rs.10,000/-only	Dy.No.3319 (R&I) 11-04.2019 Rs.20,000/- Dy.No.4922 (R&I) 30-04.2019 Rs.100,000/- *Applied Source of Pellets:* *M/s Spansules, India*
10.	C-Yalta 90mg Capsule Each capsule contains: Duloxetine HCl enteric coated pellets eq. to Duloxetine … 90mg (Manufacturer's Specifications)	070797	Initial date of Reg. 24-08-2011 (Source of Pellets: M/s Spansules formulation , India) Last Renewal applied on 22-03-2016 with Rs.10,000/- Pellets are being imported from India and the firm has submitted renewal fee of Rs.10,000/- only	Dy.No.3933(R&I) 18-04.2019 Rs.20,000/- *Applied Source of Pellets:* *M/s Spansules, India*

11.	Anvol 2.5mg Tablet Each tablet contains: Nebivolol (as HCl) …..2.5mg (Manufacturer's Specifications)	081780	Initial date of Reg. 07-10-2016	Dy.No.2909 (R&I) 08-04.2019 Rs.20,000/-
12.	Anvol 5mg Tablet Each tablet contains: Nebivolol (as HCl) …..5mg (Manufacturer's Specifications)	081069	Initial date of Reg. 22-06-2016	Dy.No.2910 (R&I) 08-04.2019 Rs.20,000/-
13.	Anvol 10mg Tablet Each tablet contains: Nebivolol (as HCl) …..10mg (Manufacturer's Specifications)	081781	Initial date of Reg. 07-10-2016	Dy.No.2911 (R&I) 08-04.2019 Rs.20,000/-
14.	Tracetol Tablet Each film coated tablet contains: Tramadol hydrochloride …37.5mg Paracetamol…..325mg (USP Specifications)	083188	Initial date of Reg. 15-03-2017	Dy.No.3623 (R&I) 15-04.2019 Rs.20,000/-
15.	Angiwell-XR 500mg Tablet Each extended release tablet contains: Ranolazine….500mg (As per innovator's specifications)	083190	Initial date of Reg. 15-03-2017	Dy.No.3314(R&I) 11-04.2019 Rs.20,000/-
16.	Angiwell-XR 1000mg Tablet Each extended release tablet contains: Ranolazine….1000mg (As per innovator's specifications)	083191	Initial date of Reg. 15-03-2017	Dy.No.3315(R&I) 11-04.2019 Rs.20,000/-
17.	Uricontrol 5mg Tablet Each film coated tablet contains: Solifenacin succinate….5mg (Manufacturer's Specifications)	081070	Initial date of Reg. 22-06-2016	Dy.No.3626(R&I) 15-04.2019 Rs.20,000/-
18.	Uricontrol 10mg Tablet Each film coated tablet contains: Solifenacin succinate….10mg (Manufacturer's Specifications)	081071	Initial date of Reg. 22-06-2016	Dy.No.3627 (R&I) 15-04.2019 Rs.20,000/-
19.	Zerogout 40mg Tablet Each film coated tablet contains: Febuxostat….40mg (Manufacturer's Specifications)	081062	Initial date of Reg. 22-06-2016	Dy.No.3624(R&I) 15-04.2019 Rs.20,000/-
20.	Zerogout 80mg Tablet Each film coated tablet contains: Febuxostat….40mg (Manufacturer's Specifications)	081063	Initial date of Reg. 22-06-2016	Dy.No.3625(R&I) 15-04.2019 Rs.20,000/-

The management of the firm has provided following documents:-

i. Applications on CTD along with Original Fee challan for each product as mentioned in Column V.
ii. Copies of initial letters of registration and renewal status as stated in column IV above.
iii. Section approval of M/s Aspin verified from Licensing Division's letter for renewal of DML (dated 09th June, 2016) confirming following sections;
   - Tablet (General)

- Capsule (General)
- Liquid Syrup
- Ointment/ Cream.

iv. Copy of last GMP inspection report of M/s Aspin, Karachi dated 08th August, 2018 indicating "Satisfactory" level.
v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 03-April 2019 & 31-12-2018.
vi. DML of M/s Aspin dated 31st May, 2015.

Decision: Registration Board decided as follows:

i. Cancellation of registration of products at S.No. 2 and 3 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. 2and 3 in the name of M/s. Aspin Pharma (Pvt.) Ltd, Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900.
iii. Deferred products at S.No. 4-6 & 11-20 as requisite Form 5-F is incomplete.
iv. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP). Furthermore, label claims shall be standardized (where required) as per standard approved by Reference Regulatory Authorities.
v. Deferred the request w.r.t products at S.No.1 for submission of evidence of approval status of applied formulation by Reference Regulatory Authorities.
vi. Deferred the request w.r.t products at S.No.7-9 for confirmation of renewal status & submission of complete documents/information regarding source of pellets.
vii. Deferred the request w.r.t products at S.No.10 for confirmation of renewal status & submission of deferential fee along with complete documents/ information regarding source of pellets.

Case No.7. 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:

I	II	III	IV	V
Sr. No.	**Name of Drug(s)**	**Reg.No.**	**Registration History**	**Remarks**
1.	Divestra Tablet Each tablet contains: Cyproterone acetate .....2mg Ethinyl estradiol…0.035mg (Manufacturer's specification)	073476	Initial date of Reg. 05-10-2012 Change of Brand Name from "Acne-Heal") to "Divestra" 27-05-2016 Last Renewal 15-08-2017 with fee of Rs.10,000/-	Dy.No.3619 (R&I) 15-04.2019 Rs.70,000/- Standard formulation approved by MHRA is "Film coated"
2.	U-Progest 100mg Capsule Each soft gel capsule contains: Progesterone (Micronized)….100mg (Manufacturer Specifications)	070796	Initial date of Reg. 24-08-2011 Last Renewal 22-03-2016	Dy.No.3628 (R&I) 15-04.2019 Rs.70,000/-
3.	U-Progest 200mg Capsule Each soft gel capsule contains: Progesterone (Micronized)...200mg (Manufacturer Specifications)	073498	Initial date of Reg. 27-11-2012 Last Renewal 28-09-2017 with Rs.10,000/-	Dy.No.3629 (R&I) 15-04.2019 Rs.70,000/-

The management of the firm has provided following documents:-

i. Applications on CTD along with original fee challan for each product as mentioned in Column-V.
ii. Copies of initial letters of registration and renewal status as stated in Column-IV above table.
iii. Section approval (Soft Gel Capsule General & Tablet Hormone) of M/s. OBS Pakistan (Pvt.) Ltd. Karachi verified from Licensing Division's letter for renewal of DML (dated 08th July, 2015).
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 03-April-2019.
vi. Consent/NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi 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.

Decision: Registration Board decided to defer the applications as requisite Form 5-F is incomplete.

Case No.8. Request for Change in Registration Status of Products from M/s AGP Ltd, B-23- S.I.T.E Karachi To M/s. AGP Limited, D-109 S.I.T.E., Karachi.

M/s. AGP Limited, D-109 S.I.T.E., Karachi has requested for change of registration status of following products from M/s AGP Ltd, B-23-C S.I.T.E Karachi to their name. Details are given as under:

S.No.	Reg. No.	Name of Drug(s)	Registration History	Remarks
I	II	III	IV	V
1	013583	Ceclor 50mg/ml Drops Each ml contains:- Cefaclor as Monohydarte…….50mg	Products are registered in the name of **M/s AGP (Pvt) Ltd, B-23-S.I.T.E Karachi** on contract manufacturing from **M/s. AGP Health Care (Pvt) Limited, Karachi** & permission is valid upto 30.06.2020	Dy.No.1447/DDC (Reg-II) 18-08-2017 Rs.20,000/- Cefaclor 50mg/ml Suspension approved by Health Canada, however, cancelled post market.
2	007176	Ceclor 125mg Suspension Each 5ml contains:- Cefaclor as Monohydrate……125mg		Dy.No.1445/DDC (Reg-II) 18-08-2017 Rs.20,000/- UK MHRA approved.
3	053182	Ceclor 187mg Suspension Each 5ml contains:- Cefaclor as monohydrate.....187mg		Dy.No.1443/DDC (Reg-II) 18-08-2017 Rs.20,000/- USFDA approved
4	007175	Ceclor 250mg/5ml Suspension Each 5ml contains:- Cefaclor as Monohydrate……. ..250mg		Dy.No.1449/DDC (Reg-II) 18-08-2017 Rs.20,000/- USFDA approved

5	018560	Ceclor MR 375mg Tablet Each modified release tablet contains:- Cefaclor …… 375mg		Dy.No.1446/DDC (Reg-II) 18-08-2017 Rs.20,000/- USFDA approved Cefaclor 375mgExtended Release Tablet. Standard formulation contains: "Cefaclor as monohydrate… 375mg"
6	017812	Ceclor MR 500mg Tablet Each modified release tablet contains:- Cefacloras monohydarte……500mg		Dy.No.12045/(R&I) 16-08-2017 Rs.20,000/- USFDA approved Cefaclor 375mgExtended Release Tablet.
7	017813	Ceclor MR 750mg Tablet Each modified release tablet contains:- Cefaclor asmonohydarte…….. 750mg		Dy.No.1550/DDC (Reg-II) 18-08-2017 Rs.20,000/-
8	007177	Ceclor 250mg Capsule Each capsule contains:- Cefaclor as Monohydarte ……. 250mg		Dy.No.1444/DDC (Reg-II) 18-08-2017 Rs.20,000/- USFDA approved.
9	007178	Ceclor 500mg Capsule Each capsule contains: Cefaclor as Monohydarte……..500mg		Dy.No.1448/DDC (Reg-II) 18-08-2017 Rs.20,000/- UK MHRA approved.
10	001071	Keflex 100mg/ml Drops Each ml contains:- Cephalexin …… 100mg		Dy.No.1422/DDC (Reg-II) 16-08-2017 Rs.20,000/- UK MHRA approved.
11	001070	Keflex 125mg Suspension Each 5ml contains:- Cephalexin …… 125mg		Dy.No.1421/DDC (Reg-II) 16-08-2017 Rs.20,000/- USFDA approved.
12	003757	Keflex 250mg Suspension Each 5ml contains:- Cephalexin……. ….. 250mg		Dy.No.1423/DDC (Reg-II) 16-08-2017 Rs.20,000/- USFDA approved.
13	001072	Keflex 250mg Capsule Each capsule contains: Cephalexin…….250mg		Dy.No.1419/DDC (Reg-II) 16-08-2017 Rs.20,000/- USFDA approved.
14	001073	Keflex 500mg Capsule Each capsule contains:- Cephalexin…… ….. 500mg		Dy.No.1420/DDC (Reg-II) 16-08-2017 Rs.20,000/- USFDA approved.

The management of the firm has provided following documents:-

i. Application with Original Fee challan for each product as mentioned in Colum V.
ii. Copies of initial letters of registration & approval letter for extension in contract manufacturing permission as stated in column IV above.
iii. Copy of last GMP inspection of M/s AGP Limited, D-109 S.I.T.E., Karachi (DML 000044), dated 09-08-2018, indicating "Good" level. Furthermore, it has been stated in

the report that the management informed that this facility is dedicated for manufacturing of Cephalosporins only.

iv. NOC from M/s. AGP Ltd, B-23- S.I.T.E Karachi dated 19-03-2019.
v. Approval of Licensing division for Change in title from M/s AGP Healthcare (Pvt) Ltd, D-109, S.I.T.E Karachi DML 000044 to M/s AGP Limited, D-109 S.I.T.E Karachi 000044 vide letter no. F.2-49/84-Lic (Pt) dated 29-12-2016.
vi. Approval of Licensing division for Change in title from M/s AGP (Pvt) Ltd, B-23, S.I.T.E Karachi DML 000348 to M/s AGP Limited, B- 23 S.I.T.E Karachi 000348 vide letter No. F.2-3/92-Lic (Vol-II) dated 29-12-2016.
vii. DML of M/s AGP Healthcare (Pvt) Ltd, D-109, S.I.T.E Karachi dated 15-07-2014.
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. 1-6 & 8-14 from the name of M/s AGP (Pvt) Ltd, B-23- S.I.T.E Karachi.
ii. Approved registration of products at S.No. 1-6 & 8-14 in the name of M/s. AGP Limited, D-109 S.I.T.E., Karachi.
iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).
iv. Deferred the request w.r.t products at S.No.7 for submission of evidence of approval status of applied formulation by Reference Regulatory Authorities.

Case No.9. Request For Change in Registration Status of Products From M/s Opal Laboratories (Pvt) Ltd.Karachi To M/s. ScilifePhamra (Pvt.) Ltd., Karachi.

Registration Board in its 286th meeting considered the request of M/s. ScilifePhamra (Pvt.) Ltd; 16, K.O.C.H.S, Amir Khusro Road P.O.Box # 8935 Karachi-75350 for change in registration status of following products from M/s. Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E, Landhi, Karachi to their name:-

S.No.	Name of Drug(s)	Reg.No.
1.	Vpride 1mg Tablet Each tablet contains:- Glimepride ……. 1mg	039350
2.	Vpride 2mg Tablet Each tablet contains:- Glimepride ……. 2mg	039351
3.	Vpride 3mg Tablet Each tablet contains:- Glimepride ……. 3mg	039352
4.	Vpride 4mg Tablet Each tablet contains:- Glimepride ……. 4mg	039353

The management of the firm provided Form-5 and fee of Rs. 20,000/- for each product and provided following products:-

i. Form-5 along with fee of Rs.20,000/-each.
ii. Copy of initial letter of registration and renewal status.
iii. NOC from M/s. Opal Laboratories (Pvt.) Ltd, Karachi (dated nil).
iv. Copy of inspection report dated 10-07-2018.

M/s Opal Laboratories has submitted 3 times renewal fee on 18-10-2017 & 30-11-2017 under SRO 1005(I)/2017.

Decision of M-286: *Registration Board deferred the case for confirmation of renewal status from RRR section and submission of fresh NOC from M/s Opal Laboratories (Pvt.) Ltd, Karachi, issued within last 6 Months.*

RRR section has confirmed the renewal status i.e "Regisatrtion Board acceded to request of the firm and decided to grant/regularize the renewal till 11-07-2020. Furthermore, the firm has also submitted fresh NOC from M/s Opal Laboratories (Pvt.) Ltd, Karachi dated 12-03-2019

Decision: Registration Board decided as follows:

i. **Cancellation of registration of products at S.No. 1-4from the name of M/s Opal Laboratories (Pvt.) Ltd, LC-41, L.I.T.E, Landhi, Karachi**
ii. **Approved registration of products at S.No. 1-4 in the name of M/s. ScilifePhamra (Pvt.) Ltd; Plot No.FD-57/58-A-2 Korangi Creek Industrial park (KCIT) 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 Getz Pharma (Pvt) Ltd. Karachi To M/s. ScilifePhamra (Pvt.) Ltd., Karachi.

M/s. ScilifePhamra (Pvt.) Ltd; Plot No.FD-57/58-A-2 Korangi Creek Industrial park (KCIT) Karachihas requested for change in registration status of following products from M/s Getz Pharma (Pvt) Ltd. Karachi to their name:-

S.No.	Reg. No.	Name of Drug and Composition	Registration History	Remarks
I	II	III	IV	V
1.	019865	M-Low 5mg Tablets Each tablet contains: Amlodipine 5mg	Initial Reg. Date: 15-04-1997 Change of Brand name from "Amlocard" to "Lopicard" 15-05-2001 Change of Brand name from "Lopicard" to "M-Low" 11-02-2009 Last renewal applied on 10-12-2013	Dy.No.2466/DDC(Reg-II) 17-12-2018 Duplicate Dossiers 14-11-2016 Rs.20,000/-
2.	019866	M-Low 10mg Tablets Each tablet contains: Amlodipine 10mg	Initial Reg. Date: 15-04-1997 Change of Brand name from "Amlocard" to "Lopicard" 15-05-2001 Change of Brand name from "Lopicard" to "M-Low" 11-02-2009 Last renewal applied on 10-12-2013	Dy.No.2466/DDC(Reg-II) 17-12-2018 Duplicate Dossiers 14-11-2016 Rs.20,000/-

The management of the firm has provided following documents:-

i. Duplication Dossier with Fee Challan of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column IV above.
iii. Section approval of M/s Scilifeverified from Panel Inspection Report for grant of DML (dated 29-03-2016) confirming following sections;
   - Tablet (General)
   - Capsule (General)
   - Sachet (General)
   - Dry Suspension Oral (General)
   - Ointment/ Cream (General)
iv. Copy of last GMP inspection report of M/s Scilife, Karachi dated 10-07-2018 indicating "Good" level.
v. NOC from M/s. Getz (Pvt.) Ltd; Karachi dated 19th November, 2018.

W.r.t renewal status, RRR section has confirmed that the case was discussed in 288th Meeting of the Board and minutes are under process. As per decision recorded in minutes (Provided by RRR Section) renewal is w.e.f 11-02-2014 to 10-02-2019. However, it is clarified by RRR section that "inadvertently validity of renewal has been recorded 10-02-2023 which will be corrected as 10-02-2024. Case will be placed in forthcoming meeting of Registration Board for the information of the Board. It is for your information that validity of renewal is according to the change of brand name i.e., 11-02-2009. Firm applied for the renewal of year 2019 on 20-12-2018 and accordingly the correct validity of renewal will be w.e.f 11-02-2019 to 10-2-2024."

Decision: Registration Board decided as follows:

i. Cancellation of registration of products at S.No. 1-2from the name of M/s Getz Pharma (Pvt) Ltd. Karachi.

ii. Approved registration of products at S.No. 1-2 in the name of M/s. Scilife Phamra (Pvt.) Ltd; Plot No.FD-57/58-A-2 Korangi Creek Industrial park (KCIT) Karachi. For verification of duplicate fee challan, procedure shall be adopted as approved vide 285th meeting of Registration Board.

iii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).

Case No.11. Request for Change in Registration Status of Products From M/s Aspin Pharma (Pvt) Ltd, Plot 10 & 25, Main Korangi Industrial Rd, Sector 20, Korangi Industrial Area, Karachi To M/s. AGP Limited, B-23-C S.I.T.E, Karachi

M/s. AGP Limited,B-23-C S.I.T.E, Karachi has requested for change in registration status of following products from M/s Aspin Pharma (Pvt) Ltd, Plot 10 & 25, Main Korangi Industrial Rd, Sector 20, Korangi Industrial Area, Karachi 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.	Roscor 5mg Tablet Each film coated tablet contains:- Rosuvastatin calcium eq. to Rosuvatatin ……. 5mg (As per *Innovator's Specification)	089300	21-12-2018 Rs. 120/10's	Dy.40(19-02-2019) Rs.20,000/-

2.	Roscor 10mg Tablet Each film coated tablet contains:- Rosuvastatin calcium eq. to Rosuvatatin …….. 10mg (As per *Innovator's Specification)	089301	21-12-2018 Rs. 200/10's	Dy.41(19-02-2019) Rs.20,000/-
3.	Roscor 20mg Tablet Each film coated tablet contains:- Rosuvastatin calcium eq. to Rosuvatatin …….. 20mg (As per *Innovator's Specification)	089302	21-12-2018 Rs. 388/10'	Dy.39(19-02-2019) 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/-.
ii. Copies of initial letter of registration as stated in column IV above.
iii. Panel Inspection Report of M/s. AGP Limited,B-23-C S.I.T.E, Karachi renewal of DML as evidence of approved section (Tablet General) dated 28-04-2016.
iv. Copy of last GMP inspection of M/s. AGP Limited,B-23-C S.I.T.E, Karachi dated 16-10-2018, indicating "Good" level of GMP compliance.
v. NOC from M/s Aspin Pharma (Pvt) Ltd, Plot 10 & 25, Main Korangi Industrial Rd, Sector 20, Korangi Industrial Area, Karachi dated 04-02-2019

Later on, the firm, vide letter No. RA/DRAP/070-19 dated 13-03-2019 had applied for withdrawal from application for transfer of registration of Roscor Tablet range. (Dy.No.166/DD(R-I) dated 20-03-2019)

Decision: **Registration Board acceded to the request of M/s. AGP Limited, B-23-C S.I.T.E, Karachifor withdrawal of their application regarding change in registration status of above mentioned products from M/s Aspin Pharma (Pvt) Ltd, Plot 10 & 25, Main Korangi Industrial Rd, Sector 20, Korangi Industrial Area, Karachi to their name.**

Case No.12. Request for Change in Registration Status of Products From M/s Standpharm Pakistan (Pvt) Ltd, Lahore ToM/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 Standpharm Pakistan (Pvt) Ltd, Lahore to their name. The details are given as under:

S.No.	Name of Drug(s)	Reg.No.	Registration History	Remarks
I	II	III	IV	V
1	Alcuflex Tablet Each tablet contains:- Naproxen Sodium……550mg	020286	Initial Reg. Date 16-10-1997 Change of Brand name 08-12-2016	Dy.7362 R&I (20.02.2019) Rs.20,000/- The firm has now applied for film coated tablet as per standard formulation approved by RRAs.

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. Copy of Approval of Change of Brand Name **(Alcuflex)**dated 08.12.2016.

iv. 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.
v. 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.
vi. NOC from M/s Standpharm Pakistan (Pvt) Ltd, Lahore dated 01-02-2019.
vii. Undertakings in the light of SOP approved vide M-283 of Reg. Board.

RRR section has confirmed on 25-04-2019 that renewal application of above mentioned product has been received within due date.

Decision: Registration Board decided as follows:

i. Cancellation of registration of Alcuflex Tablet (R# 020286) from the name of M/s Standpharm Pakistan (Pvt) Ltd, 20-Km Ferozepur Road Lahore.

i. Approved registration of Alcuflex Tablet in the name of M/s. ICI Pakistan Ltd., S-33, Hawkes Bay Road, Karachi.Furthermore, formulation shall be standardized to "Film coated tablet" as per firm's request &standard formulation approved by Reference Regulatory Authorities.

ii. Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).

Case No.13. Request for Change in Registration Status of Products From M/s Surge Laboratories (Pvt.) Ltd., Sheikhupura To M/s. Nabiqasim Industries Pvt Ltd. Karachi.

M/s. Nabiqasim Industries Pvt Ltd.,17/24 Korangi Industrial Area Karachi has requested for change in registration status of following products from M/s Surge Laboratories (Pvt.) Ltd.,10-Km Faisalabad Road BhikhiDistt.Sheikhupurato their name. The details are given as under:

S.No.	Reg.No.	Name of Drug(s)	Registration History	Remarks
I	II	III	IV	V
1	065657	Prekacin Injection 500mg Each 2ml contains: Amikacin Sulphate eq. to Amikacin…….500mg (USP Specifications)	Initial Reg. Date 02-09-2010	Dy.2439(11.12.2018) Rs.20,000/-
2	059975	Prekacin Injection 250mg Each 2ml vial contains: Amikacin Sulphate eq. to Amikacin…….250mg (USP Specifications)	Initial Reg. Date 09-09-2009	Dy.2438(11.12.2018) Rs.20,000/-
3	059976	Prekacin Injection 100mg Each 2ml vial contains: Amikacin Sulphate eq. to Amikacin…….100mg (USP Specifications)	Initial Reg. Date 09-09-2009	Dy.2437(11.12.2018) 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. The firm has provided evidence for approval of **Lyophilized/ vial (General) Section**issued vide Licensing Division's Letter No.F.2-20/85-Lic (Vol.III) (M-227) dated20-06-2011.

iv. Copy of last GMP inspection of M/s. Nabiqasim dated 02-08-2018, indicating "acceptable" level of GMP compliance& availability of "small volume Lyophilized Injectables".
v. Copy of DML of M/s. Nabiqasim dated 12-07-2014.
vi. NOC from M/s Surge Laboratories (Pvt.) Ltd dated 08-05-2019.

Decision: **Registration Board deferred the request M/s. Nabiqasim Industries Pvt Ltd. Karachifor confirmation regarding approval status of requisite manufacturing facility i.e., Liquid vial (General) (SVP) Sectionform Licensing Division of DRAP.**

Case No.14. Request for Change in Registration Status of Products From M/s Webros Pharmaceuticals, Rawat To M/s Bloom Pharmaceuticals (Pvt) Ltd.,Hattar.

M/s Bloom Pharmaceuticals (Pvt) Ltd., plot No. 30 Phase I & II Industrial Estate Hattar. has requested for change in registration status of following products from M/s Webros Pharmaceuticals, Plot No. 1 Street No. 10 National Industrial Zone Rawatto their namealong with few changes as per details mentioned against each.

S.#	Reg. No.	Product for registration with generic name	Registration History	New proposed brand name	Remarks
I	II	III	IV	V	VI
1.	034707	Wefen 400mg Tablet Each tablet contains:- Ibuprofen……..400mg	Initial Date of Registration 02-12-2004 RRR section has confirmed that RB acceded to request of the firm & decided to grant/ regularize the renewal till 01-12-2019	Blufen	Dy.No.3820/R&I 26-12-2016 Rs.20,000/- **The case was deferred in M-267 for clarification of renewal status.** The firm has also requested for following changes in the currents status of Registration letter:- i. From plain tablet to film coated tablet ii. USP Specification Status of renewal needs to be confirmed. UK MHRA approved as Film coated tablet.
2.	034694	Webnizole Tablet Each tablet contains:- Metronidazole…….200mg	Initial Date of Registration 02-12-2004 RRR section has confirmed that RB acceded to request of the firm & decided to grant/ regularize the renewal till 01-12-2019	Zonid	Duplicate Dossier with Yellow copy of fee challan of Rs.20,000/- dated 23-12-2016 **The case was deferred in M-267 for clarification of renewal status.** The firm has also requested for following changes in the currents status of Registration letter:- i. From plain tablet to film coated tablet ii. USP Specification Status of renewal needs to be confirmed UK MHRA approved as Film coated tablet.

3.	066389	Mycelex Cream Each gm contains: Clotrimazole…… 1% w/w	Initial Date of Registration 01-10-2010 RRR section has confirmed that RB acceded to request of the firm & decided to grant/ regularize the renewal till 30-09-2020	Blotrim	Dy.No.3818/R&I 26-12-2016 Rs.20,000/- UK MHRA approved.
4.	066391	Acticin Cream Each tube contains: Permithrin……..5% w/w (Webros Specifications)	Initial Date of Registration 01-10-2010 RRR section has confirmed that RB acceded to request of the firm & decided to grant/ regularize the renewal till 30-09-2020	Blotrix	Dy.No.3817/R&I 26-12-2016 Rs.20,000/- UK MHRA approved.
5.	066393	Alicam Gel Each gel contains: Piroxicam……0.5% (USP Specifications)	Initial Date of Registration 01-10-2010 RRR section has confirmed that RB acceded to request of the firm & decided to grant/ regularize the renewal till 30-09-2020	Sandan	Dy.No.3815/R&I 26-12-2016 Rs.20,000/- UK MHRA approved.
6.	066394	Adan Gel Each gel contains: Diclofenac as Diethyl Ammonium Salt……1gm (BP Specifications)	Initial Date of Registration 01-10-2010 RRR section has confirmed that RB acceded to request of the firm & decided to grant/ regularize the renewal till 30-09-2020	Valoron	Dy.No.3816/R&I 26-12-2016 Rs.20,000/- The firm has also requested for following changes in the currents status of Registration letter:- "Each 1g gel contains: Diclofenac Diethylammonium 11.6mg eq. to Diclofenac Sodium….10mg." UK MHRA approved.

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. Section approval verified from Licensing Division letter No. F.3-5/93-Lic (Vol-II) dated 11-04-2016 confirming following sections.

- Tablet General
- Cream Ointment General

iv. Copy of last GMP inspection of M/s Bloom Pharmaceuticals, Hattar, dated 07-04-2018, indicating "Good" level of GMP compliance.
v. NOC from M/s Webros Pharmaceuticals, Rawatdated 30-04-2019
vi. Undertakings in the light of SOP approved vide M-283 of Reg. Board.

Decision: Registration Board decided as follows:

i. **Cancellation of registration of products at S.No.1-6 from the name of from M/s Webros Pharmaceuticals, Plot No. 1 Street No. 10 National Industrial Zone Rawat.**
ii. **Approved registration of products at S.No.1-6 (along with change in brand names)in the name of M/s. Bloom Pharmaceuticals (Pvt) Ltd., plot No. 30 Phase I & II Industrial Estate Hattar. Furthermore, formulations/label claims shall be standardized as per firm's request & standard formulations approved by Reference Regulatory Authorities.**
iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

Case No.15. Issuance of Registration letter of Pyrexa 5mg & 10mg Tablets by M/s. Genome Pharmaceuticals, Hattar.

Following two products of M/s. Genome Pharmaceuticals, Hattar were approved in 264th meeting of Registration Board as dispersible tablets but because of availability of these products in reference regulatory authorities in Orally Disintegrating/Orodispersible tablets the registration letter could not be issued . Now the firm has submitted duplicate dossiers with respect to these products with correct formulation i.e. Orodispersible tablets.

1.	M/s. Genome Pharmaceuticals, Hattar.	Pyrexa 5mg Dispersible Tablets Each tablet contains:- Olanzapine …..5mg (Antipsychotic) Genome Specs	Price Not fixed yet	10's As Per SRO	Product is available and approved by US FDA as orally disintegrating tablet, and also available and approved by MHRA as orodispersible tablet specifications may be given accordingly. Name has been changed to **"Olnaz"** due to similarity with already registered products.
2.		Pyrexa 10mg Dispersible Tablets Each tablet contains:- Olanzapine …..10mg (Anti psychotic) Manufacturer's Specs	Price has not been fixed yet	10's As Per SRO	Product is available and approved by US FDA as orally-disintegrating tablet, and also available and approved by MHRA as orodispersible tablet specifications may be given accordingly. Name has been changed to **"Olnaz"** due to similarity with already registered products.

Decision of M-287: *Registration Board decided to defer the case for submission of fresh fee for both products.*

Now the firm has submitted a fresh fees of Rs.20,000/- for each product dated 6.02.2019. (Deposit Slip # 084063 & 084062 respectively).

Decision: Registration Board deferred the request of M/s. Genome Pharmaceuticals, Hattarfor submission of generic/me-too status of Olanzapine orally-disintegrating/ Orodispersible Tablet 5 mg & 10mg.

Case No.16. Correction in Letter of Drug(s) of M/s. Helix Pharma (Pvt.) Ltd; Karachi

M/s. Helix Pharma (Pvt.) Ltd; Karachi has requested for correction in formation of their following registered product:-

S.No.	Name of Drug(s) with existing formulation	Existing MRP & Pack Size	Correct MRP & Pack Size	Reg.No.
1.	Vomitron 3mg / 3ml Injection Each 3ml contains:- Granisetron as hydrochloride ……. 3mg	Rs. 253.00 / 3ml vial	Rs. 253.00 / 3ml ampoule	086056

The firm has requested to correct the pack from vial to ampoule as the firm has approved ampoule section by Licensing Division and they had also applied the drug in ampoule dosage form.

It is submitted that product was approved in 274th meeting of Registration Board as under:-

1	Name and address of manufacturer / Applicant	M/s Helix Pharma (Pvt.) Ltd., Hakimsons House, A-56, S.I.T.E., Karachi.
	Brand Name +Dosage Form + Strength	Vomitron 3mg/3ml injection
	Composition	Each 3ml contains: Granisetron as hydrochloride…….3mg
	Diary No. Date of R& I & fee	Dy. No.207; 01-06-2015; Rs.20,000/- (01-06-2015)
	Pharmacological Group	5HT3-antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	3ml x 1's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Granisetron 1mg/ml concentrate for solution for injection or infusion (MHRA approved)
	Me-too status (with strength and dosage form)	Graniset 3mg/3ml injection of M/s CCL
	GMP status	Last inspection conducted on 10-08-2017 and report concludes that firm is operating at satisfactory level of compliance with GMP.
	Remarks of the Evaluator	
	Decision:Approved.	

The above contents of the Registration Board shows that the firm has not specifically for ampoule, therefore, letter was issued with vial dosage form. There is a considerable difference between the price of vial and ampoule pack sizes for above product.

Decision of M-279: *Registration Board deferred the case for clarification from Costing and Pricing Division on the price of the above mentioned product in vial and ampoule.*

The pricing division has clarified vide letter .No.F.11-20/20148-DD(P) (M-279 Local) dated 17-01-2019. That price of Granisetron 3mg ampoule has been fixed vide SRO 252 (I)/2018 dated 21-02-2018. Division of PE&R may proceed if it is same drug.

MRP Fixed vide said SRO 252 (I)/2018 dated 21-02-2018	**MRP/ Pack issued vide Reg. Letter No. F. 3-11/2017 Reg-II (M-274) dated 18-12-2017**
Rs.3165/5x3ml Rs.633/1x3ml	Rs.253/3ml Vial

Decision: Registration Board deferred the case for seeking opinion of Costing &Pricing Division of DRAP.

Case No.17. Products of M/s S.J & G. FazulEllahie (Pvt) Ltd., E/46, SITE, Karachi approved in 215th meeting.

Registration Board in 215th meeting approved following products of M/s S.J & G. FazulEllahie (Pvt) Ltd., E/46, SITE, and Karachi. Case was again discussed in 259th meeting wherein board deferred the following product due to reasons mentioned in last column below:

Product name with specification	Demanded pack size	Decision
Vivid Suspension Each 5ml contains: Voriconazole …….200mg	60ml	Registration Board deferred the case for confirmation of me too status.

The firm has provided evidence of fee of Rs. 15,000/- dated 29th December, 2008 and Rs. 35,000/-on 24th September, 2013 and Form-5D. However, the fee challans are not original nor endorsed by STO DRAP.

Decision of M-267: *Registration Board deferred the request of the firm for verification of fee challans from Budget and Accounts.*

The firm has now provided yellow copy of deposit slip of Rs.35,000/- & photocopy of deposit slip of Rs.15,000/- along with letter of verification issued by "Federal Treasury". However, different account heads are mentioned on challan copy& verification letter.

Decision: Registration Board observed that the case pertains to verification of duplicate fee challan that has already been addressed vide its 285th meeting.

Case No.18. Correction in Price of Drug(s) of M/s. Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi.

M/s. Barrett Hodgson Pakistan (Pvt) Ltd; F/423, SITE Karachi-75700 has requested that they were granted the registration of following product with MRP Rs.770.00/20's while the price is fixed as under:-

S.#	*Regn No.*	*Product(s) with composition.*	*MRP/Pack Issued on Reg. Letter*	*Approved MRP/Pack as per Pricing Minutes*
1.	091005	Vesibar Tablet 5mg Each tablet contains:- Solifenacin succinate…….5mg equivalent to 3.8mg Solifenacin	Rs. 770.00 /20's	Rs. 779.00/20's 9th PAC

The firm has requested to grant them the correct price and remaining pack size & MRP. Extract from the minutes of 282nd meeting of Registration Board is as under:-

5.	Name and Address of Manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Pvt) Ltd. F/423 S.I.T.E.Karachi.
	Brand Name+ Dosage Form+Strength	Vesibar Tablet 5mg
	Diary No. Date of R & I & fee	Diary No:3652, 23/05/2017, Rs: 20,000/-
	Composition	Each tablet contains: Solifenacin succinate…5mg equivalent to 3.8mg Solifenacin.
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack Size & Demanded Price	10's/ Rs.550/- 14's/ Rs.770/- 20's/ Rs.1100/- 28's/ Rs.1540/- 30's/ Rs.1650/-

	Approval Status of Product in Reference Regulatory Authorities.	Solifenacin 5 mg film-coated tablets by M/s Milpharm Limited (MHRA Approved)
	Me-too Status	Solina 5mg Tablet by M/s Hilton Pharma (Reg#61212)
	GMP Status	Last Inspection conducted on 08-08-2017and report concludes that overall GMP compliance of the firm was found quite satisfactory.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	

The firm has further requested to approve the price for film coated tablet and also approve the description of the product.

Decision of 19th PRVC: *The Committee evaluated and recommended the case in light of SOP's approved by Registration Board. The request of the firm for correction in pharmaceutical form i.e. film coated tablet has been approved by the Chairman Registration Board while for correction of MRP, the case has been referred to Registration Board.*

Decision: Registration Board approved the correction in MRP of Vesibar Tablet 5mg (R#091005) from Rs. 770.00 /20's to Rs. 779.00/20's.

Case No.19. Correction in Registration letter of M/s. Atco, Labs, Karachi.

M/s Atco Laboratories Limited, B-18, S.I.T.E, Karachi-75700 have applied for correction of strength of their following registered products:

S.No	Reg.No	Name of Drug(s) with existing Composition	Name of Drug(s) with existing Composition	Remarks
I	II	III	IV	V
1	088221	Atcovate 0.05% Lotion Each gm contains:- Fluticasone Propionate ……. **0.05mg** (USP Specification)	Atcovate 0.05% Lotion Each gm contains:- Fluticasone Propionate ……. **0.5mg** (0.05% w/v) (USP Specification)	The Registration Board approved the existing formulation as mentioned in column No. III. However, correction is required in strength of Fluticasone Propionate from "**0.05mg" to "0.5mg"** andper unit claim from "**Each gm contains:"** to "**Each ml contains:"**

The management of the firm has provided following documents for this purpose:-

i. Original challan of Rs. 5000/-.
ii. Copies of initial letter of registration.
iii. Registration is valid.

Decision of M-283: *Registration Board deferred the case for confirmation of MRP fixed for "Fluticasone Propionate0.5mg/ml Lotion".*

Pricing Division has fixed the MRP of Rs.200/20ml vide 12th DPC and same has been granted to above mentioned formulation vide letter No. F. 3-13/2017 Reg-II (M-276).

Decision: Registration Board approved the correction in composition of Atcovate 0.05% Lotion (R# 088221) i.e., as under:

Atcovate 0.05% Lotion
Each gm contains:-
Fluticasone Propionate ……. 0.5mg (0.05% w/w)
(USP Specification)

Case No.20. De-Registration of Alpram Tablet of M/s. Akhai Pharmaceuticals (Pvt.) Ltd. Karachi.

M/s. Akhai Pharmaceuticals (Pvt.) Ltd; A-248, A-256 to A-259, H.I.T.E, Lasbella, Balochistan has requested they were granted the registration of following product in import and later the product was transferred from import to local contract manufacturing by M/s. Cirin Pharmaceutical (Pvt.) Ltd; for a period of 10 months (from 18-12-2006 to 17-10-2007) vide letter dated 18-12-2006:-

S.No.	Name of Drug(s)	Reg.No.
1.	Alpram Tablet Each tablet contains:- Alprazolam ……. 0.5mg	015749

Later on, contract manufacturing permission was extended till 27-05-2008 vide letter dated 28-11-2008 by M/s. Cirin Pharmaceuticals, Hattar. Subsequently the permission was extended through same manufacturer till 08-07-2009 and 30-06-2010 vide letters dated 24-07-2008 & 13-07-2009.

The firm had applied for renewal of registration of above drug on 13-12-2011 with fee of Rs. 4000/- and on 18-08-2016 with fee of Rs. 10,000/-. The case of the firm was forwarded to RRR section for confirmation of renewal status and RRRl section has forwarded the case with the remarks that the above product was registered under contract manufacturing from M/s. Cirin Pharmaceuticals (Pvt.) Ltd; Hattar and forwarded the case to Reg-II Section for processing.

In the meanwhile, the firm has submitted approval of Tablet (Psychotropic) Section by Licensing Division and requested to transfer the registration of above product in the name of their firm as they have developed their own facility. Furthermore, the firm has also provided a copy of application with fee of Rs. 20,000/- wherein the firm had applied for contract to local manufacturing on their own facility.

The case was deferred in 4th PRVC meeting for further deliberation in its next meeting.

Decision of M-279: *Registration Board deferred the case for opinion of Legal Affairs Division.*

The firm has now applied for de-registration of Alpram 0.5mg Tablet (R#015749) stating that they have been granted new registration of same molecule under Reg. No.089351 vide 280th meeting held on 15-03-2018.

Decision: Registration Board acceded to the request of M/s. Akhai Pharmaceuticals (Pvt.) Ltd; A-248, A-256 to A-259, H.I.T.E, Lasbella, Balochistan for de-registration of Alpram Tablet 0.5mg (R# 015749).

Case No.21. Request of M/s Delta Pharma, Risalpur for Extension in Contract Manufacturing Permission Along With Change in Contract Manufacturer.

M/s Delta Pharma, Risalpur has submitted 3 times renewal fee on 04-12-2017 in pursuance of SRO 1005(I)/ 2017 dated 05-10-2017 for renewal/ extension in contract manufacturing permission along with change in contract manufacturer of following products:

S.No	Reg.No	Name of Product	Previous Manufacturer	New Manufacturer	Date of applications/Fee
1.	050327	G-Xon 500mg Injection Each vial contains: Ceftriaxone (as Sodium)….500mg (USP Specification)	M/s. Medicraft Pharmaceuticals, Peshawar	M/s Bio-Lab (Pvt) Ltd., Islamabad	**04-12-2017** Rs.150,000/-

2.	044259	G-Xon 250mg Injection Each vial contains: Ceftriaxone (as Sodium)….250mg (USP Specification)	-do-	-do-	-do-
3.	044260	G-Xon 1gm Injection Each vial contains: Ceftriaxone (as Sodium)….1gm (USP Specification)	-do-	-do-	-do-

With reference to above mentioned case following facts are submitted:

i. The 3 times renewal fee in respect of above products was submitted even after expiry of deadline i.e 03-12-2017 set under the SRO 1005(I)/ 2017.

ii. The 3 times renewal fee has been submitted on 4-12-2017 while the DML status was invalid. However the firm was granted DLM (Afresh) on 18-12-2017 with Tablet (General) & Capsule (General) sections.

The Board was informed that the fee has been submitted under the head of contract manufacturing. However the firm, in its request has stated that the fee is submitted with reference to SRO 1005(I)/ 2017.

Decision of M-281: - *Registration Board observed that though the fee is submitted under SRO 1005(I)/ 2017 which address the issue of renewal of registration while this case falls in the category of extension of contract manufacturing. However, since the fee is submitted during the period when the DML of the firm was invalid so the case was deferred for soliciting the views/ comments of Legal Affairs Division of DRAP regarding validity of the fee submitted by the firm.*

Accordingly, the case was referred to Legal Affair Divisions and the said division has responded as under:

"The DML of firm is not valid on the date of submission of fee. The DML was granted afresh to the firm on 18-12-2017 while the fee was submitted by the firm on 04-12-2017. Further, the firm deposited the fee under SRO 1005 (I)/2017 under the head of contract manufacturing therefore, the application of the firm for extension in contract manufacturing cannot be entertained against the fee submitted under SRO 1005 (I)/2017. It is gain clarified that the SRO 1005(I)/2017 only covers the renewal of regular registered products and not the extension of contract manufacturing."

Decision: Registration Board deliberated the case in the light of comments submitted by Legal Affairs Division of DRAP and decided that the above mentioned request of M/s Delta Pharma, Risalpur shall not be acceded as the DML of the firm was not valid on the date of submission of fee.

Case No.22. Brand Name Resemblance of Approved Products of M/s Caliph Pharmaceuticals, Risalpur.

Registration Board, in its 279th meeting approved the following two products of M/s Calpih Pharmaceuticals, Risalpur. Detail is given as under:

Name and address of manufacturer / Applicant	Caliph Pharmaceuticals Pvt. LTD, Plot 17, Special Industrial Zone Risalpur, KPK
Brand Name +Dosage Form +Strength	Largyl Tablet 200mg
Diary No. Date of R& I & fee	Dyn# 1599, 17-1-2017, Rs, 20,000/-
Composition	Each film coated tablet contains: Metronidazole…….200mg
Pharmacological Group	Antiamoebic
Type of Form	Form 5

Finished Product Specification	USP
Pack size & Demanded Price	10x10‘s; As per SRO
Approval status of product in Reference Regulatory Authorities	Flagyl 200 mg Approved by (MHRA)
Me-too status	Flagyl of Sanofi Aventus
GMP status	Last GMP inspection Date:07-03-2017 with satisfactory cGMP compliance
Remarks of the Evaluator.	
Decision: Approved	
Name and address of manufacturer / Applicant	Caliph Pharmaceuticals Pvt. LTD, Plot 17, Special Industrial Zone Risalpur, KPK
Brand Name +Dosage Form +Strength	Largyl Tablet 400mg
Diary No. Date of R& I & fee	Dyn# 1600, 17-1-2017, Rs, 20,000/-
Composition	Each film coated tablet contains: Metronidazole…….400mg
Pharmacological Group	Antiamoebic
Type of Form	Form 5
Finished Product Specification	USP
Pack size & Demanded Price	10x10‘s; As per SRO
Approval status of product in Reference RegulatoryAuthorities.	Flagyl 400 mg Approved by (MHRA)
Me-too status	Flagyl of Sanofi Aventus
GMP status	Last GMP inspection Date:07-03-2017 with satisfactory cGMP compliance
Remarks of the Evaluator.	
Decision: Approved	

While processing for issuance of registration letter, it was identified that the applied brand name “Largyl” resembles with “Flagyl” &M/s. Caliph Pharma was advised accordingly to change brand name of their product “Largyl”. The firm responded by producing evidence that same brand name has already been granted to their registered product i.e. “Largyl 200mg Liquid Suspension” bearing registration no.079356”. The firm has also produced evidence of similar name with little variance to different firms. For example Metrogyl (Unexo lab, Reg #009498), Ferogyl (Fedro Pharma, Reg #011926), Entagyl (BJ Pharma, Reg#087946) and Resgyl (Rasco Pharma, Reg#078931).

It was later on identified that the registered brand name of M/s Caliph is “Fedragyl” instead of “Ferogyl”

Decision: **Registration Board deliberated the case regarding resemblance of brand names and observed that unlike “Largyl”, the brand names “Metrogyl”, “Fedragyl”, “Entagyl” and “Resgyl” do not closely resemble with “Flagyl”. Therefore, M/s Caliph Pharmaceuticals Pvt. Ltd, Plot 17, Special Industrial Zone Risalpur, KPK shall be directed to change the brand name of their registered product “Largyl 200mg Liquid Suspension (Reg # 079356)”.**

Case No.23. Approved Cases of Revision of Formulation

Registration Board, in its various meetings approved following cases of revision of formulation in the light of decision taken by the Board, vide its 250th meeting.

a) Revision of Formulation of Nocer 10 Suspension (Reg. No. 042966)

M/s. Bryon Pharmaceuticals, Peshawar has requested for revision of formulation of their registered product Nocer 10 suspension in the light of decision of M-250 that is reproduced below:

90. FAMOTIDINE 10 MG/5ML LIQUID SUSPENSION		
International availability	***Me too status***	***Remarks***
Not available in reference authorities	*ACICON of M/s Barret Hodgson, Karachi* *CAPSID of M/s Olive Labs, Islamabad*	*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.		

The firm has submitted a fresh dossier with revised formulation as per following details:

Reg. No.	Previous formulation	Revised formulation
042966	Nocer 10 suspension Each 5ml contains: Famotidine……..10mg	Nocer 40 Dry Suspension Each 5ml contains: Famotidine……..40mg

Detail of submissions:

i) Application on form-5 with fee of Rs.20,000/-
ii) Copy of Registration letter dated 13-04-2006
iii) Last renewal submitted on 31-03-2016 (verified from copies of submissions to the renewal section)
iv) Last inspection report dated 15-02-2017
v) Data regarding **Accelerated** stability study conducted on 3 batches (from Oct-2016-Apr-2017).

Decision of M-276: *The Registration Board approved the revision of formulation & also modification of the brand name accordingly in line with decision of its 250th meeting as per following details:*

Nocer 40 Dry Suspension: Famotidine 40mg/5ml

Accordingly, fresh registration letter was issued to M/s. Bryon Pharmaceuticals, Peshawar for Nocer 40 Dry Suspension (R#087998).

b) Revision of Formulation of Zithrox Capsule (Reg. No. 052518)

M/s. MKB Pharmaceuticals, Peshawar has requested for revision of formulation of their registered product Zithrox Capsule in the light of decision of M-250 that is reproduced below:

12. AZITHROMYCIN 500MG CAPSULES		
International availability	***Me too status***	***Remarks***
Not approved in reference drug agencies. Only 250 mg capsules are	*AZOGEN of M/s Rogen, Islamabad.*	*Not approved in reference drug agencies. Only 250 mg capsules are approved.*

approved. However, 500 mg tablets are available. *Zithromax of M/s Pfizer, UK.*	*AZOTINE of M/s Nimral Pharma, Islamabad*	*However, 500 mg tablets are available.* *When azithromycin capsules were administered with food, the rate of absorption (Cmax) of azithromycin was reduced by 52% and the extent of absorption (AUC) by 43%.* *Zithromax 250 mg capsules should be given as a single daily dose. In common with many other antibiotics Zithromax Capsules should be taken at least 1 hour before or 2 hours after food. (Ref: MHRA)*

Decision:

i. Applicants shall either revise their formulation to tablet dosage form, if not registered previously and if manufacturing facility is approved by CLB (new registration application with complete fee) or,

ii. Shall submit Pharmaceutical development data including stability, bioavailability/ bioequivalence studies within six months period.

iii. For already registered drugs, same procedure as mentioned above (at Sr. No. i& ii) shall be adopted. Otherwise show cause notice shall be issued for deregistration of drug in this formulation.

iv. All such application shall be processed on priority basis.

The firm has submitted a fresh dossier with revised formulation as per following details:

Reg. No.	Previous formulation	Revised formulation
052518	Zithrox Capsules Each capsule contains: Azithromycin as dihydrate……..500mg	Zithrox Tablet Each film coated tablet contains: Azithromycin as dihydrate……..500mg

Detail of submissions:

i) Application on form-5 with fee of Rs.20,000/-
ii) Copy of Registration letter dated 18-09-2008
iii) Last renewal submitted on 09-09-2013 (verified from copies of submissions to the renewal section)
iv) Last inspection report dated 26-12-2016
v) Data regarding stability study i.e 6 months accelerated &12 months real time conducted on 3 batches (from Mar-2016- Mar-2017).

Decision of M-276: *The Registration Board approved the revision of formulation of Zithrox Capsules to Zithrox Tablets containing "Azithromycin as dihydrate…..500mg" in line with its decision of 250th meeting.*

Accordingly, fresh registration letter was issued to M/s. MKB Pharmaceuticals, Peshawar for Zithrox Tablets (R#087999).

c) Revision of Formulation of Registered Product(s) of M/s. Akhai Pharmaceuticals (Pvt.) Karachi.

M/s. Akhai Pharmaceuticals (Pvt.) Ltd; A-248, A-256 to A-259, H.I.T.E, Lasbella, Balochistan has requested for revision of formulation of their following registered product:-

S.No.	Name of Drug(s) with existing formulation	Name of Drug(s) with demanded formulation	Reg.No.
1.	Zonacin 500mg Capsule Each capsule contains:- Azithromycin …… 500mg (BP Specification)	Zonacin 500mg Tablet Each film coated tablet contains:- Azithromycin …… 500mg (USP Specification)	070429 dated 21-04-2011

The firm has stated that after reviewing the effectiveness and dosage of capsule against the tablet formulation which contains same molecule, they believe that their formulation should be changed to tablet. The firm has stated that Azithromycin is not available in BP specification and it is available in USP specification. They have requested to correct the specification from BP specification to USP specification. The firm initially provided fee of Rs. 5000/- only along with Form -5 for above product.

The PRVC in its 4th PRVC deferred the case to provide fee of Rs. 20,000/- and Form-5 and evaluation of the case in light of 250th meeting decision of Registration Board. The management of the firm has provided relevant information along with balance fee of Rs. 15,000/- . The RRR section has informed that the renewal application of the above product received within time.

Decision of M-283: *Registration Board approved the revision of formulation of Zonacin 500mg Capsules to Zonacin 500mg Tablets with USP Specifications.*

Registration/approval letter for revised formulation of Zonacin tablet has not been issued yet.

In view of the position explained above, casesmentioned at **a)** and **b)** have been placed for deliberation regarding registration status of previously registered formulations of these products as fresh registration letters with new registration numbers have been issued for revised formulations. Furthermore, w.r.t the third case(**c)**& all such cases in future,guidance is sought for issuance of fresh registration letter or post-registration approval letter for revision of formulation.

Decision: **Registration Board observed that since the above mentioned formulations have been revised to new dosage forms. Therefore, it will be more appropriate to issue fresh registration certificates. Accordingly, the Board also directed to cancel the previously registered formulations as per following details:**

i. **Cancellation of registration of Nocer 10 suspension (R# 042966) from the name of M/s. Bryon Pharmaceuticals, Peshawar.**
ii. **Cancellation of registration of Zithrox Capsules (R# 052518) from the name of M/s. MKB Pharmaceuticals, Peshawar.**
iii. **Cancellation of registration of Zonacin 500mg Capsule (R# 070429) from the name of M/s. Akhai Pharmaceuticals (Pvt.) Ltd; A-248, A-256 to A-259, H.I.T.E, Lasbella, Balochistan.**

Case No.24. Request of M/s Abbott Laboratories (Pakistan) Limited for Correction in Composition of Citrosoda Regular.

Registration Board, in its 284th meeting, held on 31st July- 01st Aug, 2018 considered the request of M/s Abbott Laboratories (Pakistan) Ltd Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi for Change in flavor of Citrosoda (008749) i.e reproduced as under:

M/s. Abbott Laboratories (Pakistan) Ltd Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi-75120 has requested that they have the registration of following product with lemon flavor. The management of the firm has submitted application on registration dossier and fee of Rs. 20,000/- and has requested to grant them additional variant without any flavor:-

S.No.	Reg.No.	Name of Drug(s)	Demanded MRP and specs	International availability
1.	008749	Citrosoda Each sachet 4gm contains:- Sodium Bicarbonate….1.76gm Sodium Citrate ……0.63gm Citric Acid …….. 0.72gm Tartaric Acid …….. 0.89gm	100's 20's 100's 20's (The firm has stated that Citricosoda is already a registered brand of Abbott in flavors of Orange and lemon (Originator Brand)	TGA Australia Ural Sachet

Decision of M-284: *Registration Board approved the registration of above product with innovator specifications. The claim of firm regarding MRP of the product shall be referred to Cost & Pricing Division.*

The firm has informed that the formulation of Citrosoda Regular mentioned in 284th meeting is not correct as per the documents & approval submitted by the firm with application & form-5, dated 02-05-2018 & 18-07-2018. Now the firm has requested to correct the formulation as mentioned below.

S/N	Reg.#	Composition Approved in M-284	Correct composition/ gramof Sachet	Correct composition/ 4gram of Sachet	Packsize
I	*II*	*III*	*IV*	*V*	*VI*
1.	008749	Citrosoda Each sachet **4gm** contains:- Sodium Bicarbonate...1.76gm Sodium Citrate……0.63gm Citric Acid……....0.72gm Tartaric Acid.....0.89gm	CitrosodaRegular Each **gm** of sachet contains:- Sodium Bicarbonate...0.429gm Sodium Citrate……..0.153gm Citric Acid…….....0.176gm Tartaric Acid.....0.215gm	CitrosodaRegular Each **4gm** of sachet contains:- Sodium Bicarbonate …….1.716gm Sodium Citrate……....0.613gm Citric Acid…….....0..702gm Tartaric Acid……0.858gm	4gm Sachet of 20's 4gm sachet of 100's

Decision: **Registration Board approved the correction in composition of Citrosoda Regular i.e., as under:**

Citrosoda Regular
Each gm of sachet contains:-
Sodium Bicarbonate.....0.429gm
Sodium Citrate……...0.153gm
Citric Acid…….0.176gm
Tartaric Acid.....0.215gm

Case No.25. Request of M/s Safe Pharmaceuticals (Pvt) Limited, Karachi for Correction in Formulation of Fayneec Capsule 50mg

M/s Safe Pharmaceuticals, Karachi was granted approval for registration of Fayneec 50mg Capsule vide 260th meeting of Registration Board as per below mentioned detail.

S/N	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size	Remarks on the formulation (if any) including International status in stringent drug regulatory agencies / authorities Me-too status GMP status as depicted in latest inspection report (with date) by the Evaluator	Remarks by Evaluator/ Decision	Decision of M-260
1.	M/s Safe Pharmaceuticals Pvt Ltd, Karachi **Source of Pellets** M/s Vision Pharmaceuticals Kahuta road, Islamabad 15	Fayneec Capsule 50mg Each capsule contains:- Diclofenac Sodium as SR pellets……..……50mg Anti-Rheumatics USP Specifications	Form 5 Dy No. Nil dated 17-02-2010 Rs.8000 (Photocopy) & 22-05-2013 Rs.12000 (Photocopy) As per SRO	Deflamat 50mg-Kapseln by M/s Astellas Pharma GmbH Austria. Local. Mobikare 50mg by M/s Barrett Hodgson GMP compliant as per inspection report dated 09-06-2015.	Fee Rs.8000 & Rs.12,000/- are photocopy.	Approved. Photocopy fee challanswill be verified by Budget & Accounts Division and Chairman Registration Board will permit issuance of registration letter.

Later on, after verification of duplicate fee challans, registration letter couldn't be issued as the approval status of Diclofenac Sodium 50mg SR Capsule couldn't be confirmed in Reference Regulatory Authorities.However, the firm has now informed that the formulation of Fayneec Capsule 50mg mentioned in 260th meeting is not correct as per documents submitted by the firm at the time of initial application. Detail is given below:

S/N	Composition Approved in M-260	Correct Composition as per Firm's Request
I	II	III
1.	Fayneec Capsule 50mg Each capsule contains:- **Diclofenac Sodium as SR pellets……..……50mg**	Fayneec Capsule 50mg Each capsule contains:- **Diclofenac Sodium……..……50mg**

In this regard, the firm has submitted photocopies of following documents stating "Fayneec Capsule 50mg (Diclofenac Sodium)":

i. Form-5 along with fee deposit slips…..whether enteric coated granules/pellets mentioned anywhere

ii. MOH acknowledged receipt for Fee of Rs.8000/-
iii. DRAP's acknowledged receipt for Fee of Rs.12,000/-
iv. Last Inspection Report dated 31-07-2018 (Compliance level: GOOD)

Decision: **Registration Board approved the correction in formulation of Fayneec Capsule 50mg as per details mentioned vide column III of above table. The Board further directed the firm to submit an undertaking stating their applied formulation.**

Case No.26. Request of M/s. Zaynoon Pharmaceuticals, Peshawar For Grant of Afresh Registration.

The Registration Board, in 276th meeting held on 22nd - 25thNovember, 2017, declared registration of all drugs of M/s. Zaynoon Pharmaceuticals, Peshawar invalid due to invalidity of DML declared by CLB (vide 249th meeting). However, the firm was issued afresh DML No. 000358 by way of formulation, dated 11-04-2017. 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.No.	Brand Name, Composition and (Reg.No)	Dy.No./Date & Demanded Price/ Pack	Evidence of Availability in RRAs and Metoo Status Provided by Firm	Section Approval, Last Inspection Report & DML
1.	Zayfen Suspension. Each 5ml contains:- Ibuprofen……100mg (B.P Specification) Reg. No.064409	Rs.14.00 Rs.18.00 60ml 90ml	Bruphene Suspension of M/s. Abbott Karachi	Approval of Liquid Syrup Section: 13-04-2017 Last Inspection report: 11-01-2018 DML: 11-04-2017 **(Flag- A)**
2.	Nafpol 6 Plus Suspension. Each 5ml contains:- Paracetamol……250mg. (BP Specification) Reg. No.064410	Rs.15.00 60ml	Calpol 6 Plus Suspension M/s. GSK	-do-
3.	Zaycid Suspension. Each 5ml contains:- Aluminium Hydroxide…....215mg. Magnesium Hydroxide…….80mg. Simethicone……..25mg. (USP Specification) Reg. No.064411	Rs.18.00 120ml	Mylanta Antacid Original Oral Liquid Bottle of M/s. Johnson & Johnson Karachi	-do-

The firm has provided copies of challan of Rs.20,000/- for each product. They have requested to re-register the above products accordingly.

As per information obtain from QA&LT Division, based on critical observation made by FID querying routine GMP inspection on 11-10-2018, a panel has been constituted for thorough inspection of the firm for verification of observation.

S.No. Observations

1. The air curtain was not working at the male change room entrance.
2. The management has placed a basin in the change room which is advised to be removed.
3. Raw material store is very small and the passage to liquid section is also from the

receiving area for materials; which needs to be separated by some partition.

4. The firm is also advised to provide the quarantine for the received materials.
5. The raw material testing record was seen randomly but regretted to state the record was not up-to-date although QC released tags found placed on all the raw material but the data is not traceable in the QC lab.
6. Improvement is advised in the condition of the dispensing room.
7. The management is advised to change the balance in the dispensing room.
8. The management is advised to control the humidity before dispensing the Raw Material.
9. The flooring in the liquid section is in very bad condition and needs immediate improvement; especially the washing area needs replacement of tiles.
10. The management is using used bottles which should be immediately stopped as already advised in the last inspection.
11. In the QC Lab the record is not maintained and loose papers are being used for the recording of the test results; the management is directed to use ledgers for the data so it can be kept in safe custody.
12. HPLC is not in working condition, it is a very old model and needs to be replaced.
13. The management is also advised to follow official testing methods for the testing of their registered products and should buy recent official books which are mandatory for the development of their QC methods.
14. The SOP for stability testing are not satisfactory.
15. The capacity of the Stability Chamber was also not sufficient for their registered products.
16. The HPLC operator also needs training.
17. The management is advised to appoint the full time QA in-Charge with sufficient experience.
18. The management is advised to immediately do the following;
    a) Calibration of all the equipment.
    b) Preparation and up-gradation of all the SOPs of Production and QC
    c) Purchase of official books (latest edition) and preparation of testing method accordingly.
    d) Up-gradation of HPLC.
    e) Adaptation of official testing method.
    f) Training of staff.
    g) Appointment of QA staff as per rules.

Decision of M-286: *Registration Board deferred the above-referred case till the firm complies with GMP requirements.*

The firm has now provided the latest GMP Panel Inspection Report dated 12-12-2018, conducted for the verification of the compliance/ improvements of the firm with reference to last inspection dated 11-01-2018.

Conclusion:

The firm's management has rectified most of the observations of previous inspection. They have purchased Karl Fischer apparatus and also submit the invoice of FTIR and it will be delivered to them in two months time. In light of above mentioned observations it is concluded that the firm is now operating at "Good" level of GMP Compliance.

Decision: Registration Board decided as under:

i. **Approved the grant of registration for products at S.No. 1 & 2 of above table.**

ii. **Deferred the product at S.No.3 for submission of evidence confirming approval status of applied formulation in Reference Regulatory Authorities.**

Case No.27. Registration of Co-Dep 12/25 Capsule of M/s. Nabiqasim Industries Private Limited, Karachi.

Registration Board, in its 237th meeting considered the following product of M/s Nabiqasim Industries Private Limited, Karachi as per below mentioned details:

Sr. No	Name of firm(s)	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application, Diary No. & Form	Remarks
1.	M/s NabiQasim Karachi	Co-Dep 12/25 Capsule Each capsule contains: Olanzapine ……12 mg Fluoxetine HCl…..25 mg (Anti psychotropic)	10's 14's 20's 30's	As per PRC	18-11-2011 Dy.No.372 Form-5 Rs.8000/- Rs.52,000/- 24-1-2013	

Decision of M-237: *The board referred the cases to committee comprising of Brig.(R).Prof. Dr. Muzammil Hasan Najmi (Member Registration Board), Dr. TaufeequrRehman, Assistant Professor, Department of Pharmacy, Quaid-e-Azam University, Islamabad (Member Registration Board), DDG (Reg-II) and concerned DDC for securitization, verification of codal requirements and recommendations for me-too registration applications. The recommendations of committee will be submitted to Chairman, Registration Board for decision.*

Minutes of Expert Committee of Drug Registration Board

Name of firm(s)	Name of drug(s) & Composition	Proposed Pack size	Demanded Price	Date of application, Diary No. & Form	Remarks
M/s NabiQasim Karachi	Co-Dep 12/25 Capsule Each capsule contains: Olanzapine ……12 mg Fluoxetine HCl……..25 mg (Anti psychotropic)	10's 14's 20's 30's	As per PRC	18-11-2011 Dy.No.372 Form-5 Rs.8000/- Rs.52,000/- 24-1-2013	Deferred for confirmation of me-too status

The firm has now referred to 248th meeting of Registration Board, wherein, it has been stated that a number of formulations including above mentioned formulation will be considered for registration by Registration Board and thus the Board advised P E & R Division to place all deferred cases in agenda of the meeting. However, their deferred application has not been put on agenda.

In this regard, the firm has provided the following documents& requested for grant of registration:

i. Photocopy of Acknowledgement Receipt of Registration Application dated 16-11-2011.
ii. Photocopies of fee deposit slips of Rs.8,000/- & Rs.52,000/-.
iii. Evidence for approval status of applied formulation in USFDA (As mentioned in below table)

Company	Drug Name	Active ingredient	Strength	Dosage Form/Route
Lilly	Symbyax	Fluoxetine HCL ; Olaznzapine	EQ 25mg Base EQ 12mg Base	Capsule :Oral

Decision: **Registration Board approved the grant of registration with "USP Specifications" for Co-Dep 12/25 Capsule" of M/s. Nabiqasim Industries Private Limited, Karachi.Formulation/ Label claim shall be standardized in accordance with the standard formulation approved by Reference Regulatory Authorities. Furthermore, for verification of fee challan, procedure shall be adopted as approved by the Board vide its 285th meeting.**

Case No.28. Request For Change in Formulation (Dosage form)of Products Approved in the Name of M/s Le Mendoza Pharmaceutical (Pvt) Ltd, Karachi.

Registration Board, in its 277th meeting held on 27-29th December, 2017, approved the change in registration status of following products from M/s Chas. A Mendoza Karachi to its new title i.eM/s. Le Mendoza Pharmaceuticals (Pvt.) Ltd., Karachi.

Sr. No.	Reg. No.	Name of product along with composition	Initial Date of Reg.	Fee along with date	Remarks	Renewal validity till
1.	058642	Azocam DS Capsules Each capsule contains: Azithromycin as dihydrate … 500mg	10/10/2009	(Due date: 09-10-2014) Rs.30,000/- 04-12-2017	Locally Manufactured	09-10-2019
2.	017658	Ciprocam Capsule 250mg Each capsule contains:- Ciprofloxacin Hcl eq. to Ciprofloxacin …250mg	18/07/1995	(Due date: 17-07-2015) Rs.30,000/- 04-12-2017	Locally Manufactured	17-07-2020
3.	017659	Ciprocam Capsules 500mg Each capsule contains:- Ciprofloxacin Hcleq to Ciprofloxacin …500mg	18/07/1995	(Due date: 17-07-2015) Rs.30,000/- 04-12-2017	Locally Manufactured	17-07-2020

The approval letter of above mentioned products to new title of the firm were pending due to non-availability of above mentioned formulations in "Capsule" dosage form in RRAs.However, these formulations are available in Tablet dosage form.

Now the firm has requested for revision of above mentioned formulations to "Tablet" dosage form & submitted fresh applications on Form-5 along with fee of Rs.20,000/- for each product.(Dy.Nos. 43736, 16322, 16323/R&I. with date 24-12-2018& 03-05-2018 respectively)

Decision: **Registration Board decided as under:**

i. **Cancellation of registration of products at S.No. 1-3 of above table.**
ii. **Approved the grant of new registrations for revised formulations of above mentioned products at S.No. 1-3 in "Tablet dosage form".**

Case No.29. Approved Products of M/s SNB Pharma (Pvt) Ltd. Peshawar.

Registration Board in its 237th& 238th meeting considered the following products of M/s SNB Pharma (Pvt) Ltd. Peshawar as per below mentioned details:

M-237

ANOMALY

Decision:-The Registration Board referred the applications (after submission of differential fee for registration) to committee comprising Brig. (R). Prof. Dr. Muzammil Hassan Najmi (Member Registration Board), Dr. Taufeeq Ur Rehman, Assistant Professor, Department of Pharmacy, Quaid-e-Azam University, Islamabad (Member Registration Board), DDG (Reg-II) and concerned DDC's/ADC's for scrutiny, verification of codal requirements and recommendations for me-too registration applications. The recommendations of committee will be submitted to the Chairman, Registration Board for decision.

S. No	Name of Firms	Name of Drugs /label Claim	AU	Price	Date	Remarks	Current Status
1.	M/s. SNB Pharmaceuticals Peshawar **New License**	Diclo-P 75 mg Tablets Each film coated tablet contains:- Diclofenac Potassium……75 mg (Antirheumatic)	10's	As Per SRO	24-5-2011	Approved / Remaining 4 / 6	Applied pack size: 3x10's Decision of M-258 regarding de-registration of instant formulation.
2.	-do-	Domp 10 mg Tablets Each tablet contains:- Domperidone ……..10 mg (Anti-Dopamineragic)	50's	As Per SRO	-do-	Do	Applied pack size: 10's
3.	-do-	SNfer Tablets Each tablet contains:- Iron (III) hydroxide Polymaltose ≡ Iron (Element)...100 mg Folic Acid…….0.35 mg (Anti-anaemic)	10's	As Per SRO	-do-	do	Applied pack size: 3x10's
4.	-do-	L-Floxin 250 mg Tablets Each film coated tablet contains:- Levofloxacin Hemihydrate ≡ Levofloxacin... 250mg (Quinolone)	10's	As Per SRO	-do-	do	-
5.	-do-	L-Floxin 500 mg Tablets Each film coated tablet contains:- Levofloxacin Hemihydrate ≡ Levofloxacin.. 500mg (Quinolone)	10's	As Per SRO	-do-	do	-
6.	-do-	SNVasc Tablets Each tablet contains:- Amlodipine (as besylate)…..5 mg (Calcium Antagonist)	2x10's	As Per SRO	-do-	do	-
7.	-do-	Neuromine Tablets Each film coated tablet contains:- Mecobalamine..500 mcg (Antianamic)	100's	As Per SRO	-do-	do	Standard formulation approved by RRAs is "sugar coated"

							Applied pack size: 2x10's
8.	-do-	Naprox 275 mg Tablets Each film coated tablet contains:- Naproxen Sodium……275 mg (Antirheumatic)	20's	As Per SRO	-do-	do	Applied pack size: 1x10's
9.	-do-	Naprox 550 mg Tablets Each film coated tablet contains:- Naproxen Sodium ..550mg (Antirheumatic)	20's	As Per SRO	-do-	do	Applied pack size: 1x10's
10.	-do-	Diclo-S 50 mg Enteric Coated Tablets Each enteric coated tablet contains:- Diclofenac Sodium……..50 mg (Anti-rheumatic)	10's	As Per SRO	-do-	do	Applied pack size: 3x10's
11.	-do-	L-Vcit 10 mg Tablets Each film coated tablet contains:- Levocetirizine (as 2HCl) …..10 mg (Antihistamine)	10's	As Per SRO	-do-	do	-
12.	-do-	Famo 40 mg Tablets Each film coated tablet contains:- Famotidine……..40 mg (H2- Blocker)	10's	As Per SRO	-do-	do	-
13.	-do-	SNalfa Tablets Each tablet contains:- Alfacalcidol …..0.5 µg (20.I.U.) (Vitamin D analogue)	3x10's	As Per SRO	-do-	do	-
			M-238				
S. No.	**Name of Firms**	**Name of Drugs /label Claim**	**AU**	**Price**	**Date**	**Remarks**	
14.	M/s. SNB Pharmaceuticals, Peshawar	Famot 10mg Suspension Each 5ml contains:- Famotidine……10mg (H2 Blocker)	60ml	As Per SRO	22-5-2012	Approved subject to correction in composition However the Registration Board advised the Registration sections to again review the Registration Dossiers	Decision of M-250 regarding revision of formulation.

						before issuance of Registration letters	
15.	-do-	Cefim 200mg Dry Suspension Each 5ml contains;- Cefixime……200mg (Cephalosporin)	30ml 60ml	As Per SRO	-do-	-do-	Standard formulation contains "Cefixime as trihydrate….200 mg/5ml"

Original dossiers along with fee challans of products at S.No.1-13 of above table have been retrieved from record. However, recommendations of committee could not be retrieved.Furthermore, the firm has now requested for issuance of registration letter & provided following documents:

i. Copy of DML dated 20-09-2012.
ii. Evidence for Approval of following sections:
   - Tablet (General)
   - Capsule (General)
   - Dry Suspension (General)
   - Liquid Syrup (General)
   - Cephalosporin (Capsule & Dry Powder Suspension)
iii. Last Inspection report dated 17-10-2018Conclusion is as under,

The firm has finished maintenance work and the plant is ready for production activities. The firm had already requested for approval of start production after their volunteer stop production to regulate then supply of medicines to market. They are committed to comply cGMP guidelines. The panel agrees with the firm for resumption of their production after volunteer stop production.

Decision: Registration Board decided as under:

i. Approved grant of registration for the products at S.No. 2-6, 8-10 & 12-13 of above table.
ii. Rejected the product at S.No.1 in accordance with the decision taken by the Board vide its 258th meeting.
iii. Deferred the products at S.No.7 & 15 for submission of revised formulation as approved by Reference Regulatory Authorities along with requisite fee for revision.
iv. Deferred the product at S.No.11 for submission of evidence confirming approval status in Reference Regulatory Authorities.
v. Deferred the product at S.No.14 in accordance with the decision taken by the Board vide its 250th meeting.

Case No.30. Change in Formulation of Approved Product of M/s Noa Hemis Pharmaceutical, Karachi

Registration Board in its 256th meeting approved the following product of M/s NoaHemis, Karachi

S/N	Name and address of manufacturer / Applicant	Brand Name (Proprietary name + Dosage Form + Strength) Composition Pharmacological Group Finished product Specification	Type of Form Initial date, diary Fee including differential fee Demanded Price / Pack size	International status in stringent regulatory agencies Me-too status GMP status as depicted in inspection report (dated)	Decision
1	M/s NoaHemis Pharmaceuticals , Plot # 154, Sector 23, Korangi Industrial Area, Karachi	Clinac Gel Each gram contains Clindamycin Phosphate 20mg Anti acne USP specifications	Form 5 Rs. 20000/- vide Dy. No. 167 dated 17-9-2011 & 10-04-2014 Pack size of 10gm Rs.145/-	MHRA approved Dalacin Dalacin–Pfizer GMP compliant section vide inspection report of panel dated 02-2-2015.	Approved

The firm has now requested for change in above mentioned formulation to "Clindamycin Phosphate eq. to Clindamycin 10mg (1%w/w), stating the reason of non-availability of applied formulation in Reference Regulatory Authorities. Detail is given below:

S/N	Name of Product applied for registration	Previously Applied Formulation	Revised Formulation
1.	Clinac 1% Gel	Each gram contains: Clindamycin Phosphate.....20mg	Each gram of gel contains: Clindamycin Phosphate eq. to Clindamycin……10mg (1%w/w)

In this regard, the firm has submitted fresh application along with fee of Rs.20,000/- and last inspection report dated 28-02-2019 for renewal of DML.

Decision: Registration Board approved the change in formulation of Clinac Gel as per following details:

Clinac 1% Gel
Each gram of gel contains:
Clindamycin Phosphate eq. to Clindamycin……10mg (1%w/w)

Case No.31. 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 RazzaqJawinda) and Area FID (Syed Hakim Masood) on 16th April, 2015. The panel was of the view to recommend Registration of Xenase Nasal Spray (OlopatadineHCl 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 Sprayand 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:

4. Prof Ghulam Sarwar, Dean Faculty of Pharmacy, Jinnah University for Women (Member Registration Board)
5. Mr. Abdul Rasool Shaikh, Area FID, DRAP, Karachi.
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:

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. 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.
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 procurement 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 nasal solution?	The firm has written and authorized protocols for the product development.
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 "Patanase" manufactured by Alcon Laboratories USA.
16	Have you performed comparative dissolution studies?	N/A
17	Do you have product development (R&D) section	The firm has R&D section which include facilities for manufacturing.
18	Do you have necessary equipment available in product development section for development of API Nasal Spray?	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.

<table>
<tr><th>Sr. No.</th><th>Question</th><th>Observation by panel</th></tr>
<tr><td></td><td></td><td>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:
Real Time: 30°C and 65% RH
Accelerated: 40°C and 75% RH,
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.</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 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.</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 given by any other lab?</td><td>Not Applicable</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 API and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.</td></tr>
<tr><td>29</td><td>Do your method of analysis stability indicating?</td><td>The firm’s method of analytical testing has stability indicating parameters.</td></tr>
<tr><td>30</td><td>Do your HPLC software is 21CFR compliant?</td><td>The HPLC software is 21CFR Compliant as per record available with the firm.</td></tr>
<tr><td>31</td><td>Can you show Audit Trail reports on API testing?</td><td>The firm showed the audit trail reports on API 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 completed both accelerated and real time stability studies however a few bottles were available</td></tr>
</table>

Sr. No.	Question	Observation by panel
		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 later on submitted following information, presented in 288th meeting of Registration Board:

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 of M-288: *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.*

The firm has now provided following information:

General Study of Water loss

on Semi permeable Packaging material (LDPE)

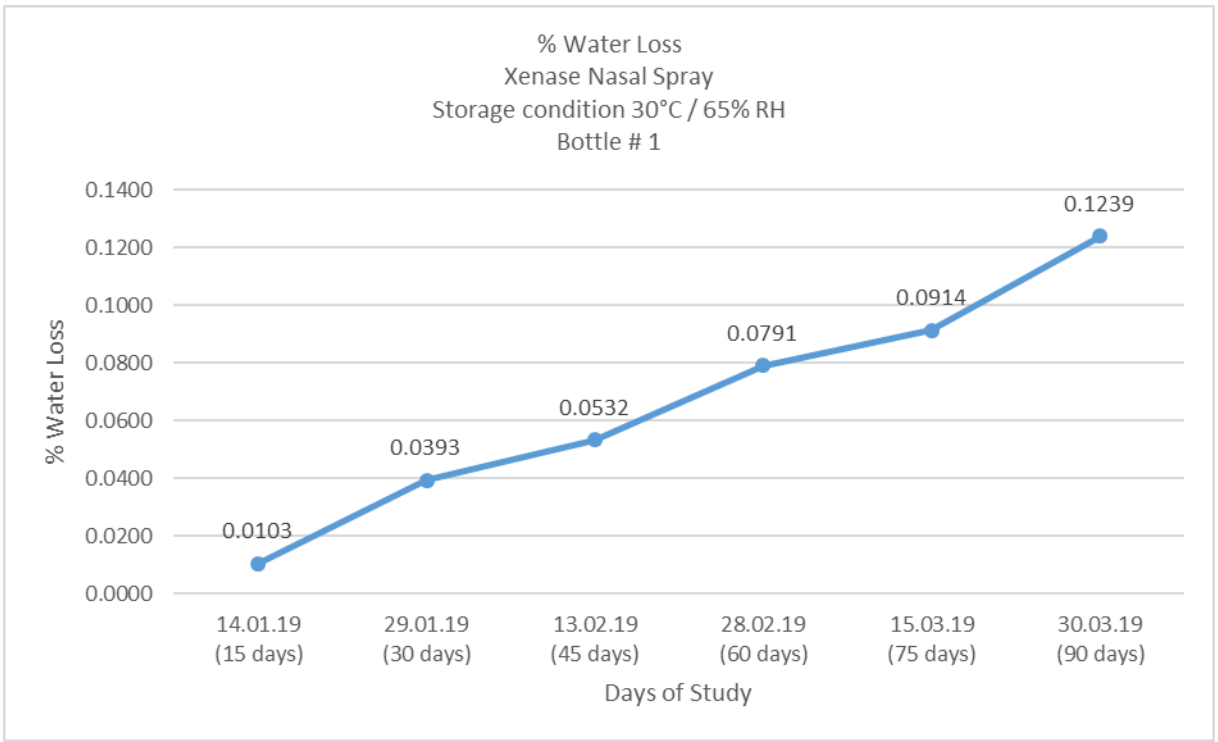
Product : Xenase Nasal Spray

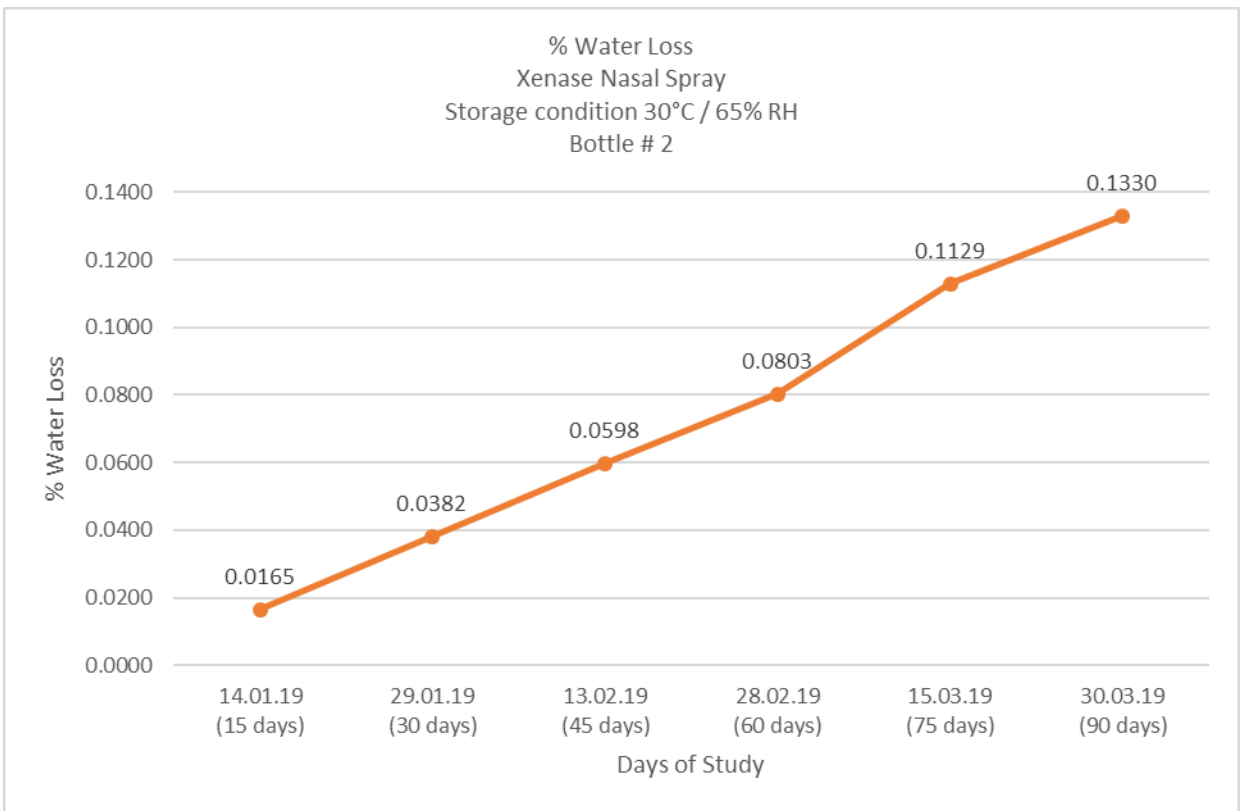
Batch No. 07T

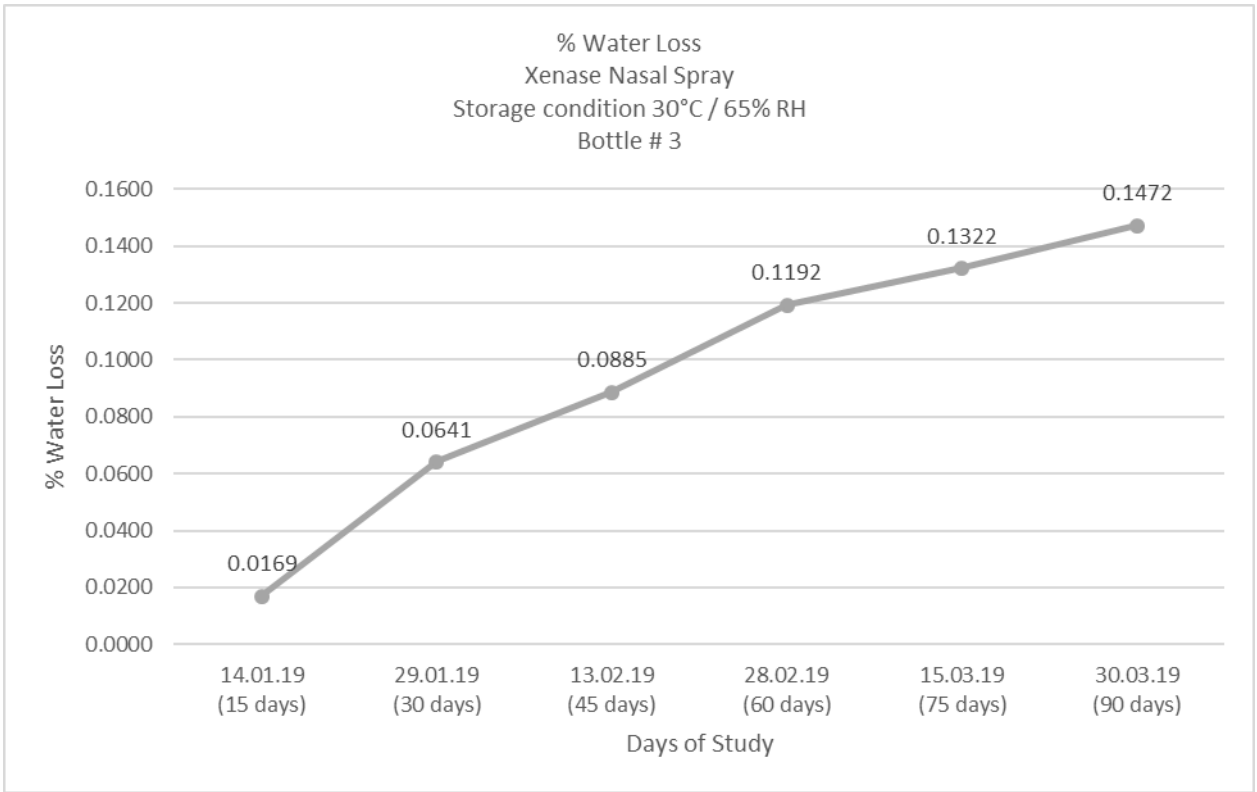
Manufacturer : Sante Private Ltd.

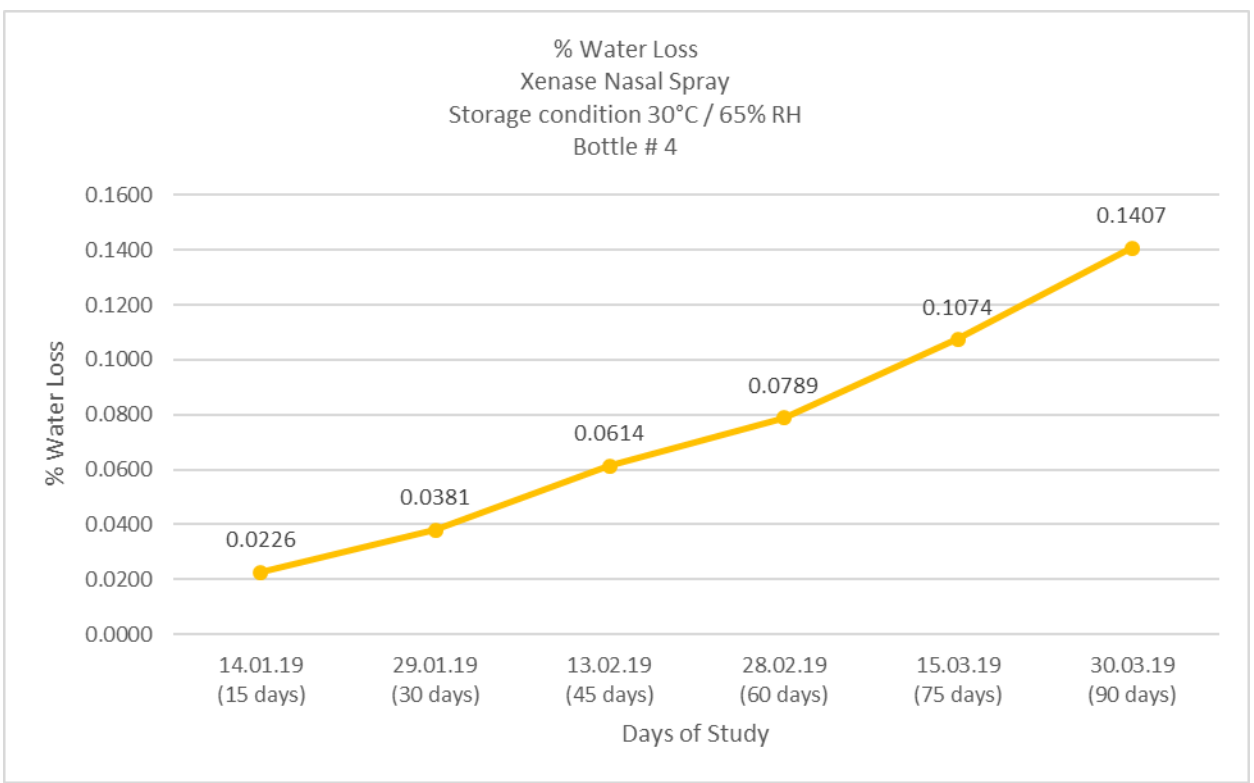
Storage condition 30°C / 65% RH

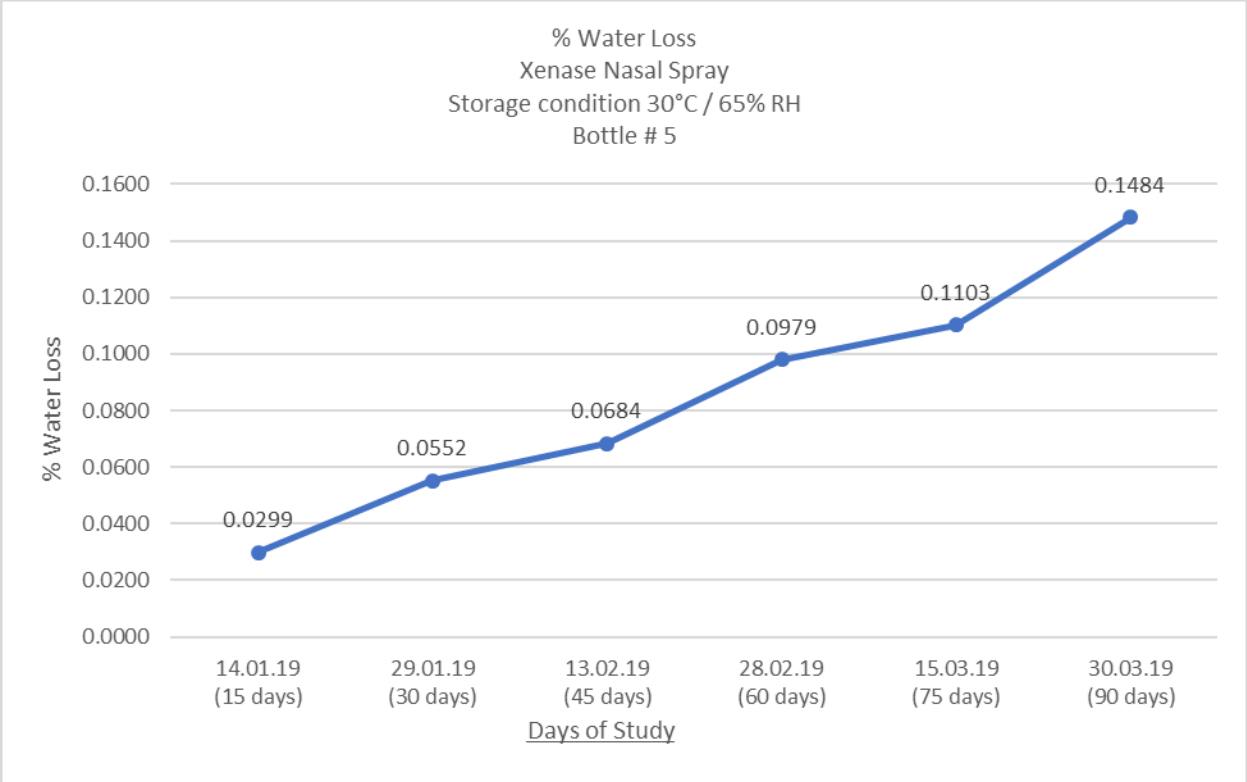
	Bottle 1	Bottle 2	Bottle 3	Bottle 4	Bottle 5
31.12.18 (Initial Weight)	25.1721	25.4129	25.4128	25.2248	25.7429
14.01.19 (15 days)	25.1695	25.4087	25.4085	25.2191	25.7352
29.01.19 (30 days)	25.1622	25.4032	25.3965	25.2152	25.7287
13.02.19 (45 days)	25.1587	25.3977	25.3903	25.2093	25.7253
28.02.19 (60 days)	25.1522	25.3925	25.3825	25.2049	25.7177
15.03.19 (75 days)	25.1491	25.3842	25.3792	25.1977	25.7145
30.03.19 (90 days)	25.1409	25.3791	25.3754	25.1893	25.7047
% Water Loss	Bottle 1	Bottle 2	Bottle 3	Bottle 4	Bottle 5
14.01.19 (15 days)	0.0103	0.0165	0.0169	0.0226	0.0299
29.01.19 (30 days)	0.0393	0.0382	0.0641	0.0381	0.0552
13.02.19 (45 days)	0.0532	0.0598	0.0885	0.0614	0.0684
28.02.19 (60 days)	0.0791	0.0803	0.1192	0.0789	0.0979
15.03.19 (75 days)	0.0914	0.1129	0.1322	0.1074	0.1103
30.03.19 (90 days)	0.1239	0.1330	0.1472	0.1407	0.1484
% loss * 1.9	Bottle 1	Bottle 2	Bottle 3	Bottle 4	Bottle 5
14.01.19 (15 days)	0.01962	0.03140	0.03215	0.04293	0.05683
29.01.19 (30 days)	0.07473	0.07252	0.12187	0.07231	0.10481
13.02.19 (45 days)	0.10114	0.11364	0.16822	0.11675	0.12990
28.02.19 (60 days)	0.15021	0.15252	0.22654	0.14989	0.18599
15.03.19 (75 days)	0.17360	0.21458	0.25121	0.20412	0.20961
30.03.19 (90 days)	0.23550	0.25271	0.27962	0.26740	0.28194


% Water Loss
Xenase Nasal Spray
Storage condition 30°C / 65% RH
Bottle # 1
% Water Loss
0.1400
0.1200
0.1000
0.0800
0.0600
0.0400
0.0200
0.0000
0.0103
0.0393
0.0532
0.0791
0.0914
0.1239
14.01.19 (15 days)
29.01.19 (30 days)
13.02.19 (45 days)
28.02.19 (60 days)
15.03.19 (75 days)
30.03.19 (90 days)
Days of Study


% Water Loss
Xenase Nasal Spray
Storage condition 30°C / 65% RH
Bottle # 2
% Water Loss
0.1400
0.1200
0.1000
0.0800
0.0600
0.0400
0.0200
0.0000
0.0165
0.0382
0.0598
0.0803
0.1129
0.1330
14.01.19 (15 days)
29.01.19 (30 days)
13.02.19 (45 days)
28.02.19 (60 days)
15.03.19 (75 days)
30.03.19 (90 days)
Days of Study


% Water Loss
Xenase Nasal Spray
Storage condition 30°C / 65% RH
Bottle # 3
% Water Loss
0.1600
0.1400
0.1200
0.1000
0.0800
0.0600
0.0400
0.0200
0.0000
0.0169
0.0641
0.0885
0.1192
0.1322
0.1472
14.01.19 (15 days)
29.01.19 (30 days)
13.02.19 (45 days)
28.02.19 (60 days)
15.03.19 (75 days)
30.03.19 (90 days)
Days of Study


% Water Loss
Xenase Nasal Spray
Storage condition 30°C / 65% RH
Bottle # 4
% Water Loss
0.1600
0.1400
0.1200
0.1000
0.0800
0.0600
0.0400
0.0200
0.0000
0.0226
0.0381
0.0614
0.0789
0.1074
0.1407
14.01.19 (15 days)
29.01.19 (30 days)
13.02.19 (45 days)
28.02.19 (60 days)
15.03.19 (75 days)
30.03.19 (90 days)
Days of Study



General Study of Water loss

on Semi permeable Packaging material (LDPE)

Product : Xenase Nasal Spray

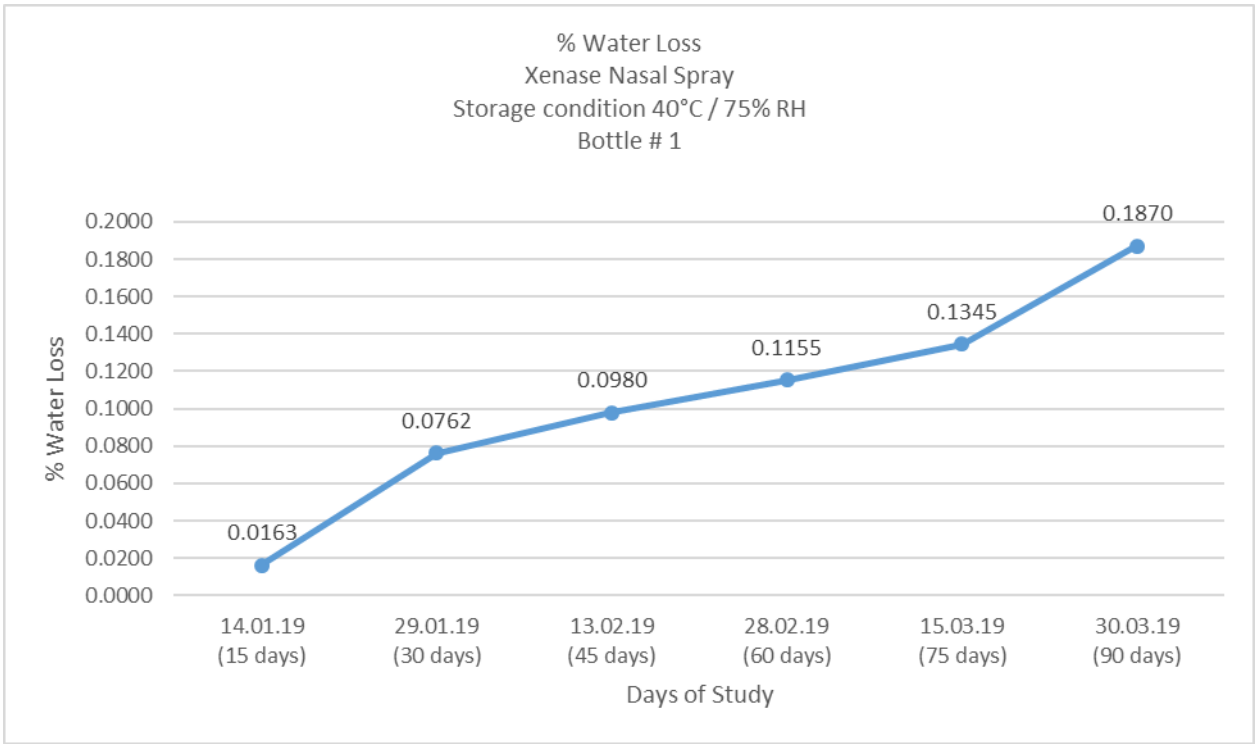
Batch No. 07T

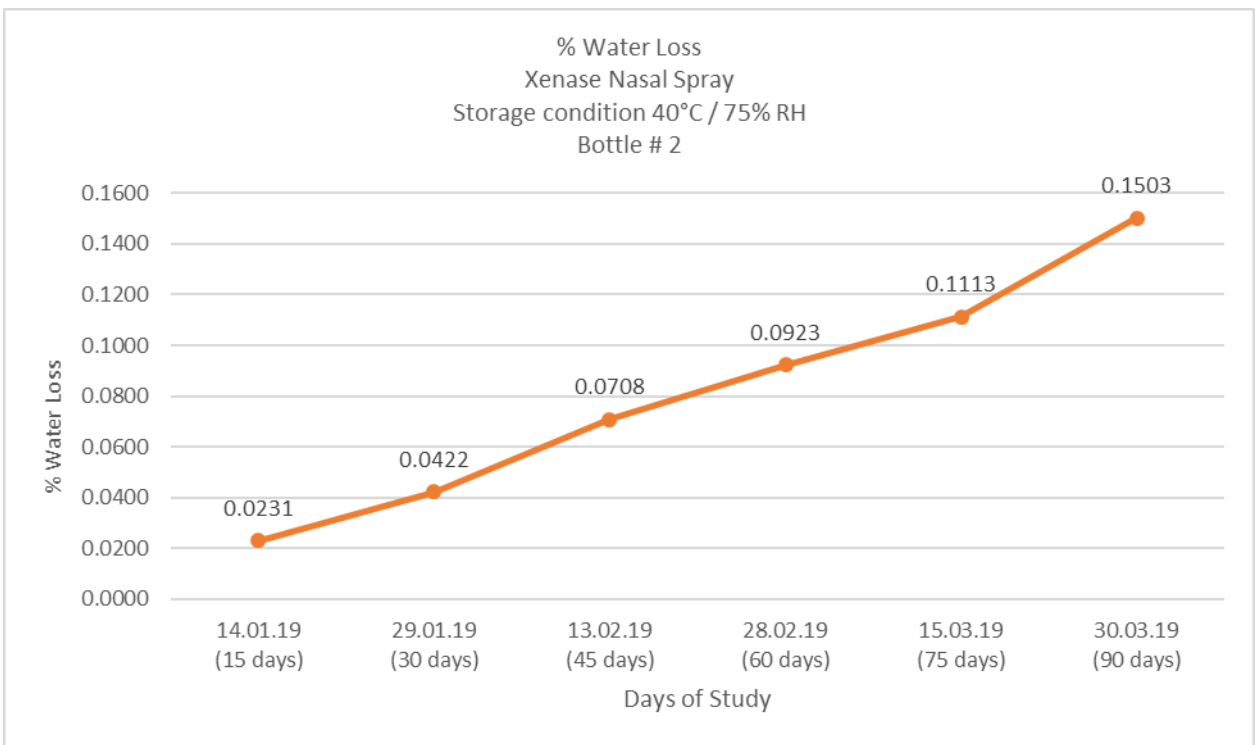
Manufacturer : Sante Private Ltd.

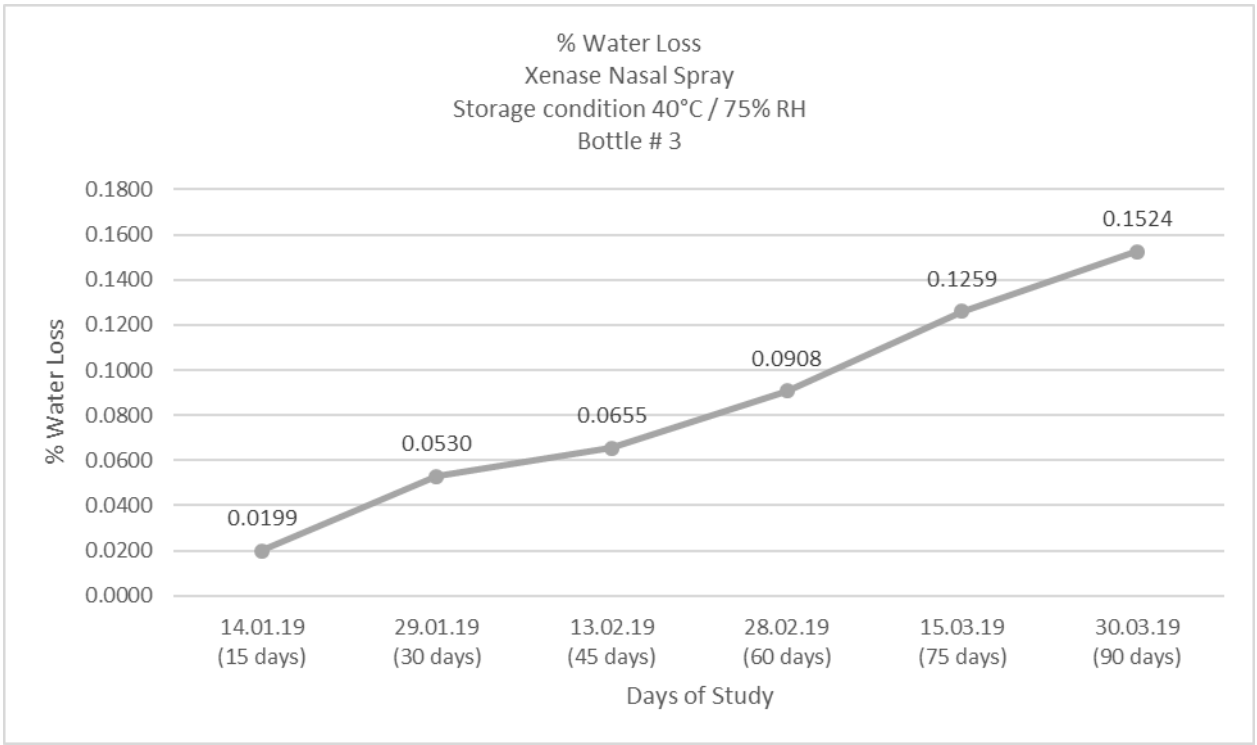
Storage condition 40°C / 75% RH

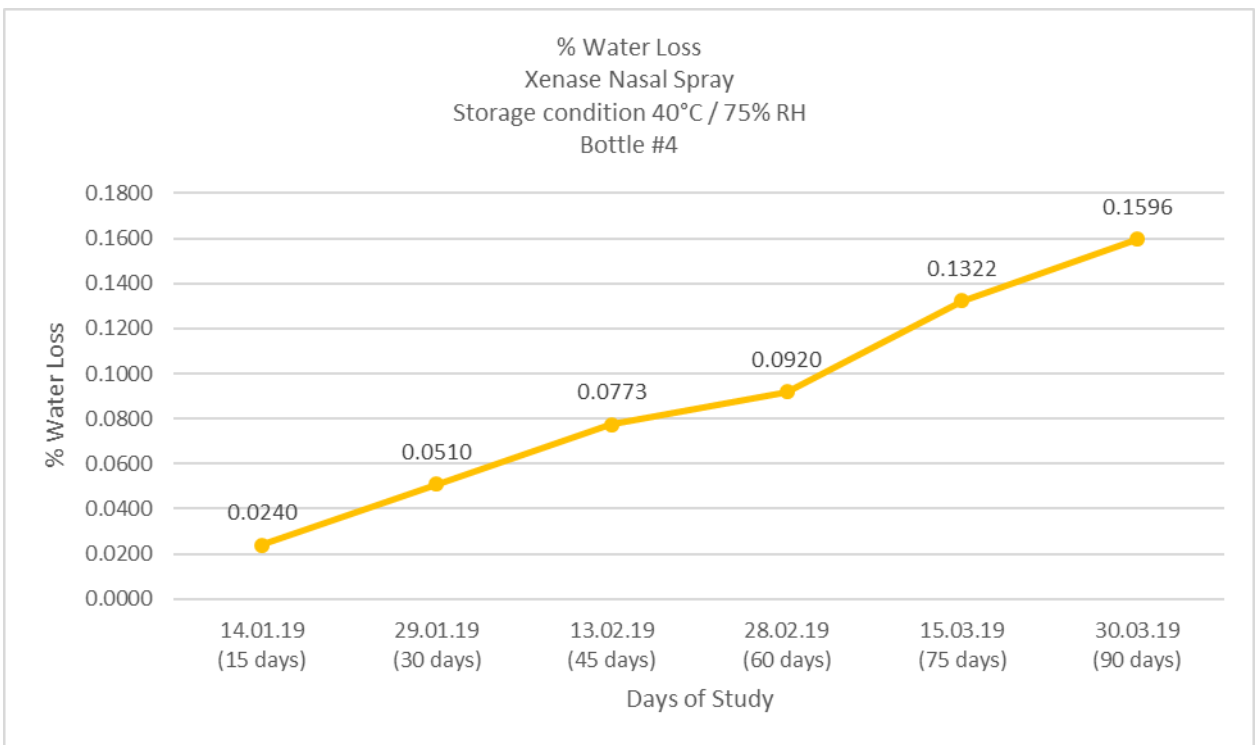
	Bottle 1	Bottle 2	Bottle 3	Bottle 4	Bottle 5
31.12.18 (Initial Weight)	25.7189	25.1465	25.6543	25.8701	25.6406
14.01.19 (15 days)	25.7147	25.1407	25.6492	25.8639	25.6322
29.01.19 (30 days)	25.6993	25.1359	25.6407	25.8569	25.6282
13.02.19 (45 days)	25.6937	25.1287	25.6375	25.8501	25.6189
28.02.19 (60 days)	25.6892	25.1233	25.6310	25.8463	25.6107
15.03.19 (75 days)	25.6843	25.1185	25.622	25.8359	25.6059
30.03.19 (90 days)	25.6708	25.1087	25.6152	25.8288	25.5971
% Water Loss	Bottle 1	Bottle 2	Bottle 3	Bottle 4	Bottle 5
14.01.19 (15 days)	0.0163	0.0231	0.0199	0.0240	0.0328
29.01.19 (30 days)	0.0762	0.0422	0.0530	0.0510	0.0484
13.02.19 (45 days)	0.0980	0.0708	0.0655	0.0773	0.0846
28.02.19 (60 days)	0.1155	0.0923	0.0908	0.0920	0.1166
15.03.19 (75 days)	0.1345	0.1113	0.1259	0.1322	0.1353
30.03.19 (90 days)	0.1870	0.1503	0.1524	0.1596	0.1697

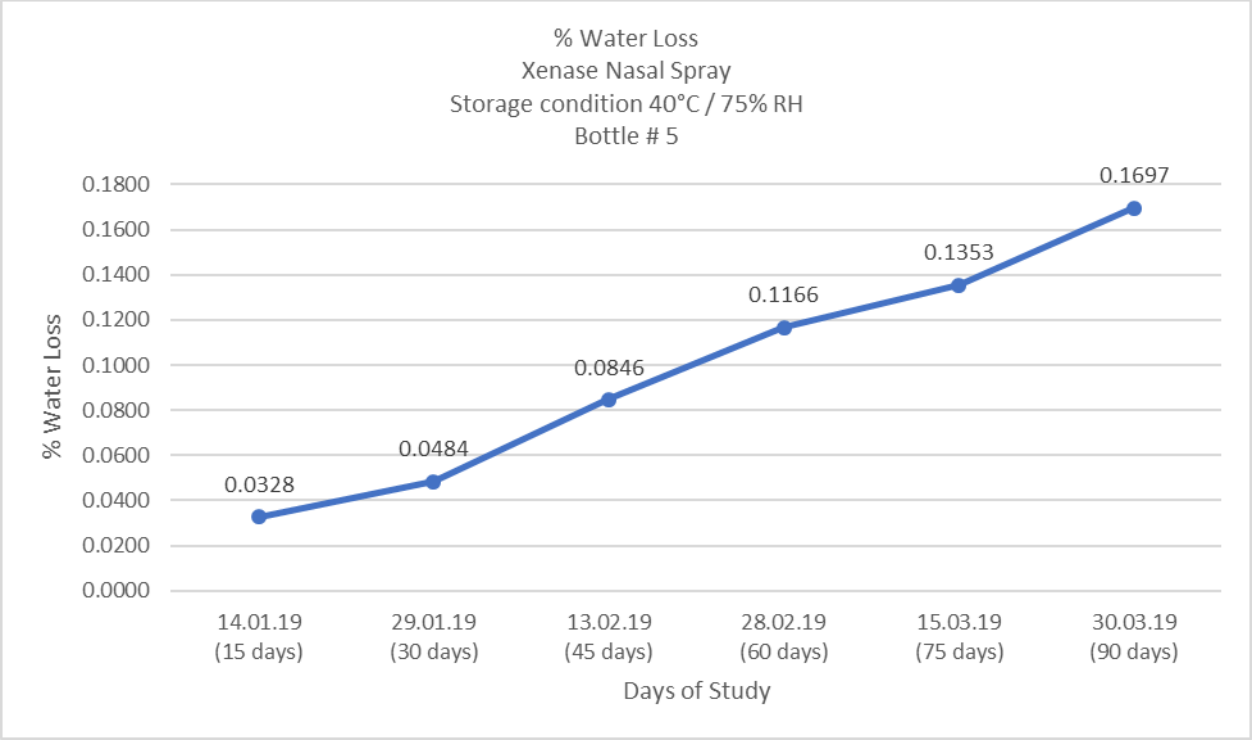
% loss * 3		Bottle 1	Bottle 2	Bottle 3	Bottle 4	Bottle 5
14.01.19	(15 days)	0.0490	0.0692	0.0596	0.0719	0.0983
29.01.19	(30 days)	0.2286	0.1265	0.1590	0.1531	0.1451
13.02.19	(45 days)	0.2939	0.2124	0.1965	0.2319	0.2539
28.02.19	(60 days)	0.3464	0.2768	0.2725	0.2760	0.3498
15.03.19	(75 days)	0.4036	0.3340	0.3777	0.3966	0.4060
30.03.19	(90 days)	0.5611	0.4510	0.4572	0.4789	0.5090






% Water Loss
Xenase Nasal Spray
Storage condition 40°C / 75% RH
Bottle # 3
% Water Loss
0.1800
0.1600
0.1400
0.1200
0.1000
0.0800
0.0600
0.0400
0.0200
0.0000
0.0199
0.0530
0.0655
0.0908
0.1259
0.1524
14.01.19 (15 days)
29.01.19 (30 days)
13.02.19 (45 days)
28.02.19 (60 days)
15.03.19 (75 days)
30.03.19 (90 days)
Days of Study


% Water Loss
Xenase Nasal Spray
Storage condition 40°C / 75% RH
Bottle #4
% Water Loss
0.1800
0.1600
0.1400
0.1200
0.1000
0.0800
0.0600
0.0400
0.0200
0.0000
0.0240
0.0510
0.0773
0.0920
0.1322
0.1596
14.01.19 (15 days)
29.01.19 (30 days)
13.02.19 (45 days)
28.02.19 (60 days)
15.03.19 (75 days)
30.03.19 (90 days)
Days of Study



Decision: **Registration Board decided to approve registration of "Xenase (Olopatadine) Nasal Spray" by M/s Sante (Pvt) Ltd.,A/97 S.I.T.E Super Highway 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.**

Case No.32. Approved Product of M/s OBS Pakistan (Pvt) Ltd., Karachi

Registration Board in its 254th meeting held on 11-12th November, 2015 considered the following product of M/s OBS Pakistan (Pvt) Ltd., Karachi as per below mentioned details:

Registration Board in 234th meetings deferred following registration application of M/s OBS Pakistan (Pvt) Ltd., Karachi for expert opinion being new formulation:

S.#	Name of firm(s)	Pack size	Demanded price
85.	Andrex Gel 1% Each 5 gm contains: Testosterone …….50 mg (Hormonals)	5gm 30's	Rs.3000/-

Now, the firm has informed that they have developed sachet filling area (Hormone) and considering the good manufacturing facility, Sachet filling area (Hormone) has been given approval by the CLB. Furthermore, Andrex Gel 1% is approved by different regulatory Authorities of the world including FDA and is available in market in various countries around the world.

The firm have provided following with their claim:

i) Approval of additional section of Sachet (Hormones) Soft Gel.
ii) Evidence of approval of above generic in TGA
iii) Approval product in FDA.

Decision of M-254: *Registration Board approved request of firm for registration of above product (Andrex Gel 1%).*

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 anda panel comprising of following members was constituted:

i. Dr. RafeeqAlam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi. (Member Registration Board)
ii. Prof. Ghulam Sarwar, Dean Faculty of Pharmacy, Jinnah University for Women, Karachi. (Member Registration Board)
iii. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Andrex (Testosterone) 1% Gel by M/s OBS Pakistan Pvt. Limited, C-14, Manghopir Road, S.I.T.E, Karachi.

Reference No: F.3-1/2016-R-II (M-254) dated 8th February, 2019.
Investigation Date and Time: 1st March, 2019. (Afternoon)
Investigation Site: Factory premises of M/s OBS Pakistan Pvt. Limited, C-14, Manghopir Road, S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s OBS Pakistan Pvt. Limited, C-14, Manghopir Road, S.I.T.E, Karachi for registration of Andrex (Testosterone) 1% Gel 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. RafeeqAlam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi. (Member Registration Board)
2. Prof. Ghulam Sarwar, Dean Faculty of Pharmacy, Jinnah University for Women, 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:

Andrex Gel 1% (Testosterone)

Q. NO.	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of API including approval from DRAP?	Firm has procured 1.5kg testosterone import from M/S. IPCA Laboratories Limited, Gujarat, India having Batch number TST/M/002/15 vide Invoice No.MUM/2014-15/5106 dated March 25, 2015 and obtained approval from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	Selection of the manufacturer has been based upon its GMP Certification and availability of DMF (open part). Supplier's assessment through postal audit.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has procured working standards of API while impurities are not included as per USP monograph.
4.	Do you have certificate of analysis of API, reference standards and impurity standards	The firm has certificate of analysis for API, Working standards of APIs.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of API Manufacturer issued by Drugs Control Administration, Government of Ghandinagar, Gujarat, India.
6.	Do you use API manufacturer method of the testing for testing API?	The firm is using API manufacturer method for testing of API which is as per USP monograph.
7.	Do you have stability studies report on API?	The firm has accelerated stability studies report of six months and 36 months real time stability reports of API.
8.	If yes, whether the stability testing has been performed as per SIM and degradation products have been quantified?	The stability testing has been performed as per USP monograph.
9.	Do you have methods for quantifying the impurities in API?	Not Applicable
10.	Do you have some remaining quantities of API, the reference standards and impurities?	The firm has remaining quantities of the API & working standard of API.
11.	Have you used pharmaceutical grade excepients?	The firm has used pharmaceutical grade excipients.
12.	Do you have documents confirming the import of used excepients?	The firm has necessary documents confirming the procurement of used excipients.
13.	Do you have test reports and other records on the excepients used	The firm has test reports & other record on the used excipients.
14.	Do you have written and authorized protocols for the development of products?	The firm has written and authorized protocols for the development of Andrex (Testosterone) Gel.
15.	Have you performed drug-excepient compatibility studies?	The firm hasn't performed drug-excipients computability study as same excipients of RLD brand used in formulation. Carbomer, Ethyl Alcohol, Isopropyl Myristate, Sodium Hydroxide
16.	Have you performed comparative dissolution studies?	Not Applicable
17.	Do you have product development (R&D) section?	The firm has dedicated area for product development comprising manufacturing & testing facilities for trial batches. However, the product in question has been developed in Hormonal Manufacturing Area.
18.	Do you have necessary equipment available in product development section for development of product?	The firm has necessary equipment for production of trial batches in Hormonal Manufacturing Area.
19.	Are the equipment in product development section qualified?	The equipment used in production and analyses of trial batches are qualified.
20.	Do you have proper maintenance/	The firm has proper maintenance / calibration /

<table>
<tr><th>Q. NO.</th><th>QUESTION</th><th>OBSERVATION BY PANEL</th></tr>
<tr><td></td><td>calibration/requalification program for the equipment used in P&D section?</td><td>requalification program for the equipment used in production and QC Lab for trial batches.</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 a team of 6 pharmacists for product development section and 2 pharmacist & 5 chemists in analysis of trial batches with operators, with suitable knowledge and training in product development.</td></tr>
<tr><td>22.</td><td>Have you manufactured stability batches for the stability studies of the product as required?</td><td>The firm has manufactured three stability batches for the stability studies with following details:<table><tr><td>Batch #</td><td>Mfg date</td><td>Batch size</td></tr><tr><td>EXP-G-01</td><td>June-2015</td><td>3.0 kg</td></tr><tr><td>EXP-G-02</td><td>June-2015</td><td>1.5 kg</td></tr><tr><td>EXP-G-03</td><td>Nov-2015</td><td>1.5 kg</td></tr></table>The Gel is packed in Alu/Alu Sachet with pack size of 1x 10’s.</td></tr>
<tr><td>23.</td><td>Do you have criteria for fixing of the batch size of stability batches?</td><td>As per statement of the firm, the criteria for fixing the batch size of stability batches is the number of sachets required for completion of stability studies.</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 book of equipment used have been available with the firm, assuring the traceability of manufacturing and analyses of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability products?</td><td>The firm has protocols for stability 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 used method for testing of stability batches of their finished product, which is stability indicating and has validated while using the working standards of API and also supported by forced degradation studies.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing used by your firm is given by another firm?</td><td>Not Applicable.</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 API and the finished products?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished products.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm method of testing is stability indicating for stability testing of their finished product, as supported by forced degradation studies.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21 CFR compliant?</td><td>The firm has used 21 CFR compliant HPLC.</td></tr>
<tr><td>31.</td><td>Can you show audit trail reports on product testing?</td><td>Audit trail initially not activated. However, now audit trail is activated from 12thmonths studies.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities degradation products and stability batches?</td><td>The firm has completed stability studies while some quantities of working standard of the API available.</td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm has completed the stability testing on the three stability batches of Andrex (Testosterone) 1% Gel.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipment used in production and analysis?</td><td>The firm has valid calibration status for the equipment used in production and analysis of Andrex (Testosterone) 1% Gel.</td></tr>
<tr><td>35.</td><td>Do proper and continuous monitoring and control are available for stability chamber?</td><td>Continuous power supply and monitoring (data loggers) are available for stability chambers. The data is properly reviewed on daily basis.</td></tr>
<tr><td>36.</td><td>Do related manufacturing area, equipment, personnel, and utilities be rated as GMP compliant?</td><td>The related manufacturing area, equipment, personnel and utilities are rated as GMP compliant.</td></tr>
</table>

CONCLUSION:

1. On the basis of risk-based approach the genuineness/authenticity of stability data submitted by the firm for registration of Andrex (Testosterone) 1% Gel is verifiable to satisfactory level.
2. The related manufacturing area, equipment, and utilities of Hormonal Section can be rated as GMP compliant and are suited for the manufacturing of Andrex (Testosterone) 1% Gel.
3. Keeping in view the above statement the panel recommends grant of registration in the name of manufacturer.

Decision: **Registration Board decided to approve registration of "Andrex (Testosterone) 1% Gel" by M/s OBS Pakistan (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.**

Case No.33. 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 2. Dosage Form 3. Composition 4. Pharmacological Group	1. Type of form 2. Type of application 3. Demanded Price/ Pack size 4. Initial date, diary 5. Date on which fee becomes complete according to type of application/ or Form (Total Fee)	1. Me-too Status 2. GMP status	Decision
1	M/s GaxoSmithKline Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi	Panadol Joint Tablet Each modified release tablet contains: Paracetamol PhEur 665mg modified release (Non narcotic Analgesic) Finished product specifications are Manufacturer	1. Form 5 A 2. 20's Rs. 200/- 3. 22-06-12 4. 18-04-13 Rs.150,000/-	1. Paracetamol-Osteo 665mg modified release tablets approved by TGA 2. New Drug 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:** M/s GaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia. **Packaging Site:** 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: 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 Certificate No. 11/0084 The facilities and operations conform to GMP as recommended WHO. Free sale: Confirms the free sale of the product in exporting country. 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. "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: 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. 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 of M-288: *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.*

In line with the above mentioned decision of the Board, the firm provided stability studies and a panel comprising of following members was constituted:

i. Dr.SaifurRehmanKhattak, Director, CDL, DRAP, Karachi.
ii. Dr. Najam us Saquib, Additional Director, DRAP Office, Karachi.
iii. Mr. Kirshan Das, Assistant Director, DRAP Office, Karachi.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Panadol Joint 665mg Tablets (Paracetamol) by M/s. GlaxoSmithKline Pakistan Limited, S.I.T.E, Karachi.

Reference No: F.3-3/2019-Reg-I (M-288) dated 29th, April, 2019.
Investigation Date and Time: 08th May, 2019 (Morning).
Investigation Site: Factory premises of M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi for registration of Panadol Joint 665mg Tablets (Paracetamol) 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.SaifurRehmanKhattak, Director, CDL, DRAP, Karachi.
2. Dr. Najam us Saquib, Additional Director, DRAP Office, Karachi.
3. Mr. Kirshan Das, Assistant Director, DRAP Office, 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:

PANADOL JOINT 665MG TABLETS

S. No	Question	Observation by Panel
1.	Do you have documents confirming the import of API including approval from DRAP?	Around 7500 Panadol joint tablets were imported in bulk from miser GskErmington Australia. Via invoice number 142 dated 18th Dec 2013. With reference to DRAP Islamabad letter # F.3-3/2012-IE/PT dated 10th July 2013. Three batches of bulk tablets were imported with batch # 131707,131708 and 131751 each of 2500 tablets. The manufacturing and expiry date of these three batches were Aug 2013 and Aug 2017 respectively. Tablets for imported in fibre drums. Approval from DRAP Karachi for the release of the consignment was obtained on 08th Jan 2014.
2.	What was the rationale behind selecting the particular manufacturer of API?	Not applicable

S. No	Question	Observation by Panel
3.	Do you have documents confirming the import of reference standard and impurity standards?	Reference standard has been imported from Hamire road, Barnard castle, co. Durham, DL12 8DT, UK bearing Catalogue number 5307 batch 8 for paracetamol, bearing catalogue number 1481 batch 4 for 4-chloroacetanilide and bearing catalogue number 5305 batch 6 for p-aminophenol.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	As above
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Not applicable.
6.	Do you use API manufacturer method of testing for testing API?	It is a bulk product tested vide the tablet manufacturing site (GskErmington Australia) method of testing.
7.	Do you have stability studies reports on API?	Although it is a bulk product however stability reports of API are also available
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability has been performed as SIM it is available with the firm.
9.	Do you have method for quantifying the impurities in the API?	Not applicable
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	API not applicable however some quantities of the reference standard and impurities are available.
11.	Have you used pharmaceutical grade excipients?	Not applicable
12.	Do you have documents confirming the import of the used excipients?	Not applicable
13.	Do you have test reports and other records on the excipients used?	Not applicable
14.	Do you have written and authorized protocols for the development of applied product?	Protocol for development is available. Complete testing of the bulk product is advised to be added in the protocol and the related tests to be performed on receipt of the bulk product. Moreover, holding time studies should also be performed for the period between receipt of the bulk product in conversion on packaging.
15.	Have you performed Drug-excipients compatibility studies?	***Not applicable***
16.	Have you performed comparative dissolution studies?	Since the product is that of innovator therefore only dissolution studies has been performed at Gsk site
17.	Do you have product development (R&D) section	Not applicable
18.	Do you have necessary equipments available in product development section for development of applied product?	Not applicable
19.	Are the equipments in product development section qualified?	Not applicable
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	Not applicable

S. No	Question	Observation by Panel
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Not applicable
22.	Have you manufactured three stability batches for the stability studies of applied product as required?	The firm has packed (blistering and cartooning) three batches with batch number 01, 02 and 03 each of 125 packs of 20s.
23.	Do you have any criteria for fixing the batch size of stability batches?	DRAP reference letter for import of bulk tablets reference as above.
24.	Do you have complete record of production of stability batches?	The firm has complete record of import of bulk product tablets (three batches) and there blistering and cartooning.
25.	Do you have protocols for stability testing of stability batches?	The firm has authorised protocol for stability testing of Panadol Joints tablets # STAB/STP-NP/968/02.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has adopted Gsk Australia Ermington method of testing. Proper method transfer studies has been conducted.
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?	As above
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has documents confirming the qualification of equipment's / instruments being used in the test and analysis bulk finished drug.
29.	Is your method of analysis stability indicating?	The firm has SIRM.
30.	Is your HPLC software is 21CFR compliant? (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 shall also be reported.)	The firm has HPLC compliant with 21CFR. audit trail reports are available
31.	Can you show Audit Trail reports on stability studies testing?	Audit trail reports on the testing are available
32.	Do you have some remaining quantities of degradation products and stability batches?	Since stability has been completed two years ago therefore no stability batch or degradation products are available with firm as such however a blister of 10 tablets batch number 03 was produced by the firm as a reference for review of the panel
33.	Do you have stability batches kept on stability testing?	Stability testing has already competed
34.	Do you have valid calibration status for the equipments used in production and analysis?	The firm has valid calibration status of equipment's
35.	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported.)	The firm has continuous monitoring and control are available for stability chamber.
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.

Conclusion:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Panadol Joint tablet is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Panadol Joint tablet.

Recommendation

1. Panadol Joint tablet is recommended for registration (bulk import and local packing) in the name of the firm.

Decision: **Registration Board decided to approve registration of "Panadol Joint Tablets (Paracetamol 665mg Modified Release)" in the name of M/s GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E., Karachi (DML 000233) as per following details:**
Bulk tablets will be imported from M/s GlaxoSmithKline Australia Pty Limited, Consumer Healthcare Division, 82 Hughes Avenue, Ermington NSW 2115, Australia and M/s. GlaxoSmithKline Pakistan Limited, F-268 S.I.T.E, Karachi will be responsible forblistering and packing oftablets alongwith final quality control release of the finished pharmaceutical product. Furthermore, first three production batches of the productwill be placed on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case No. 34. Grant of Registration OnPriority Basis In Lieu of Export Facilitation.

Registration Board, in its 288th meeting considered the following application of M/s Medisure Laboratories (Pvt.) Limited, A-115, S.I.T.E., Super Highway, Karachi on priority basis in lieu of export facilitation. Detail is as under:

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	
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: 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. • Tablet General Section is available in the firm as mentioned in the submitted section approval letter. • **Film- coating** is not applied in the master formulation. • Me- too status could **not** be confirmed. • **Stability** is required against the applied formulation.
Decision: Deferred for application on Form 5-D along with submission of differentialfee and stability study data as per the requirements of 278th meeting of Registration Board.	

Now the firm has requested to replace the above mentioned molecule with new molecule detailed below:

I	II	III	IV
Sr.No	**Molecule/Generic**	**Product Name & Composition**	**Date of Submission of Dossier**
1.	Lacosamide	Lacoste 50mg Tablet Each film coated tablet contains: Lacosamide……50mg	31-12-2018
		Lacoste 100mg Tablet Each film coated tablet contains: Lacosamide……100mg	31-12-2018
		Lacoste Injection Each 20ml contains: Lacosamide……200mg	31-12-2018

The case has been placed for deliberation whether a replacement can be made with an item i.e., already considered on priority (in lieu of export facilitation) and deferred by the Registration Board.

Decision: **Registration Board acceded to the request of M/s Medisure Laboratories (Pvt.) Limited, A-115, S.I.T.E., Super Highway, Karachi for replacement of previously deferred application of Ticagrelor 90mg Tablet with abovementioned Lacosamide Tablet Range for grant of registration on priority basis in lieu of export facilitation.**

Case No.35. Request of M/s. Muller & Phipps Pakistan (Private) Limited,Karachi .

M/s. Muller & Phipps Pakistan (Pvt.) Ltd. Uzma Court, Main Clifton Road, P.O. Box3880-Karachi-75600 has requested that they have multinational distribution network for national and multinational pharmaceuticals companies. On behalf of importers / manufacturers they always participate in the institution tender business. As per the institution requirements outer / secondary packs must be stamped / over printed with the same of institution and wording "Not for Sale". Their licensed warehouse has been approved by the Drug Regulatory Authority of Pakistan for storage of biological and non-biological products.

They have provided following documents:-

i. Drug Regulatory Authority of Pakistan, Inspectors Approval reports.
ii. Provisional Establishment Certificate to Import Medical Devices provided in schedule-D.
iii. Copy of valid sale license.
iv. Authority letters for institutions of different manufacturers.
v. Fee of Rs. 5000/- for this purpose.

They have further quoted the SRO 470(I)/2017 and the medical devices Rules 2017, as under:-

1. **Drugs (Labelling & Packing) Rules, 1986 (Rule 9A, Sub-rule (2):**
"Where the imported drugs, at the time of import, do not confirm to the provision of sub-rule (1), the person importing the drug shall make an arrangement at a local facility licensed to manufactured drugs of sell the drugs in terms of clause (i) of Rule (3) of the Drugs (Import & Export) Rules, 1976 with the prior approval of the Registration Board to print the GSI Application, before the drug is placed in to the Pakistani Market."
2. **Medical Devices Rules 2017: (Rule 38, Sub-rule (2):**
"Where a medical devices has either not been appropriately labeled, or partially labelled as mentioned in sub-rule (1), the importer on his request in this behalf may be allowed by MDB to comply with these rules relating to labeling by printing the information of establishment-license's details, enlistment or registration number, MRP or any other information which may be required by MDB at establishment's licensed premises".

They have requested that the above stated proviso should also be extended to the stamping / marketing on outer packs for Government Institution Supplies only, as the Drugs (Labeling and Packing) Rules has been amended.

The PRVC in its 14th meeting referred the case for presenting in Registration Board.

Decision of M-286: *Registration Board referred the case to Legal Affairs Division of DRAP for opinion/ comments.*

Comments furnished by Legal Affairs Division

The term "label" is defined in the Drugs Act, 1976 as display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package. As per aforesaid Act, "labeling" means all labels and other written, printed or graphic matter accompanying any drug. The act defines "manufacture" as all operations involved in the production of the drug, including labeling with a view to its storage, sale and distribution. Therefore, labeling is part of manufacturing process.

Rule 7 of the Drugs (Labeling and Packaging) Rules, 1986 deals with labeling of drugs for Government supply. The said rule stipulates that the label of a container of every drug intended for the supply to any Government agency including an autonomous body or a semi government agency shall, while complying with other labeling requirements of 1986 rules, bear the words or mark reading "Government Supply" or such other words or mark as may be required by the agency concerned.

In view of the above, labeling requirements including the addition of words "Government Supply" or "Not for Sale", being part of drug manufacturing process, has to be carried out during that process.

It is further clarified that S.R.O. 470(I)/2017 was issued to amend the 1986 rules to include barcoding requirements. Rule 3A(2) of S.R.O. 2470(I)/2017 requires an importer to make an arrangement at a local facility licensed to manufacture drugs or sell drugs to print the GS1 application, if the imported drugs do not conform to the barcoding requirements at the time of import, before the drug is placed in to the Pakistan market. The said rule only deals with barcoding requirements. The provisions of Medical Devices Rules, 2017 cannot be extended to labeling requirements of drugs under the 1986 Rules.

Decision: **Registration Board deliberated the case in the light of comment furnished by Legal Affairs Division of DRAP & decided that the request of M/s. Muller & Phipps Pakistan (Private) Limited, Karachi shall not be acceded.**

Case No. 36: Allocation Of Quota For Control Substances Ephedrine HCl for the year 2017 to M/s. Sharex Laboratories, Sadiqabad.

The case of M/s. Sharex Laboratories, Sadiqabad was considered in 275th and 286th meeting of Registration Board as per detailed below:-

Proceedings of 275th of Registration Board:

The instant case was presented based on the letter received from Assistant Director (CD) (Dated 21st Sep, 2017) wherein it has been stated that M/s Sharex Laboratories, sadiqabad applied for quota allocation of product "Tracodil syrup (Reg. 003158). The case was presented before 43rd meeting of committee on allocation of controlled drug held on 26th July, 2017, the comittee deferred the case for issuance of show cause by DRAP for manufacturing of Tracodil syrup (Reg. 003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of Tracodil syrup (Reg. 003158) 400ml pack size.

The approved pack sizes of product "Tracodil Syrup" (Reg no. 003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October 1988).

Decision of 275th meeting of Registration Board:-

Registration decided to call M/s Sharex Laboratories, Sadiqabad for personal hearing and for deliberating above mentioned matter before the Registration Board.

Proceedings of 286th meeting of Registration Board:-

Mr. Muhammad Ishfaq, production pharmacist, appeared before Registration Board and apologized on behalf of the firm for applying quota of 400ml pack size of product "Tracodil syrup (Reg.003158) without approval.

Decision of 286th meeting of Registration Board:-

Registration Board in its 286th meeting decided to refer the case to Legal Affair division for legal opinion.

Accordingly, the case was refer to Legal Affairs, Division and in response, Legal Affairs, Division has provided following opinion:-

i. That M/s. Sharex Laboratory applied for the quota allocation of product "Tracodil Syrup" (Reg.No.003158).
ii. That the Committee on Allocation of Controlled Drugs held on 26.07.2017 deferred the case for issuance of show cause by DRAP for manufacturing of "Tracodil Syrup" (Reg.No.003158) 60ml, 400ml pack without approval. It was requested to verify the status of product registration of "Tracodil Syrup" (Reg.No.003158) and 60ml (dated 27th October, 1988).
iii. That the approved pack size of the product "Tracodil Syrup" (Reg.No.003158) have been verified as per available record i.e 120ml, 450ml (National Formulary 1981) and 60ml (dated 27th October, 1988).
iv. That Mr. Muhammad Ishfaq production pharmacist, appeared in 286th meeting before Board and apologized on behalf of the firm for applying quota of 400ml pack size of product "Tracodil Syrup" (Reg.No.003158) without approval.
v. That the Registration Board in 286th meeting referred the case to Legal Affairs, Division for legal opinion.
vi. Drug Regulatory Authority of Pakistan Act, 2012 in Schedule-II A(1) (a) (vii) prohibits export, import or manufacture and sale or sell of any therapeutic goods which is not registered or is not in accordance with conditions of registration as

disclosed in the registration dossier and that has undergone pharmaceutical evaluation. Furthermore, Schedule-II(A)(c) prohibits to sell any therapeutic goods except under, and in accordance with the conditions of a license issued under this Act. In addition, Schedule-II A(a)(f) prohibit to supply an incorrect, imcomplete or misleading information when required to furnish any information under this Act or the rules.

vii. In this regard, DRAP Act, 2012 under section 27 read with schedule-III (6) provides penalty for violating the prohibitions mentioned above.

Decision: **In light of the opinion of Legal Affair's Division on the matter, Registration Board deliberated the case and decided to issue showcause notice to M/s Sharex Laboratories, Sadiqabad for violation of condition of drug registration, as follows:**

- **Cancellation of registration.**
- **Suspension of registration.**
- **Prosecution in Drug Court**

Case No. 37: CASE OF UNIVERSITY OF SARGODHA (UOS) PHARMACEUTICAL LABORATORIES, SARGODHA.

Dr. Muhammad Tahir, Haseeb, Incharge UOS Pharmaceutical Laboratories, University of Sargodha has informed that they were granted the registration drugs vide letter No.F.8-9/2017-Reg-III(M-273) dated 09-10-2018. He has further informed that a pharmaceutical industrial unit (University of Sargodha Pharmaceutical Laboratories) was established by the University of Sargodha for commercial and research purposes and requisite license was attained from Drug Regulatory Authority of Pakistan vide license No. 000859, dated 21-06-2017 for this purpose. The Syndicate of the university of Sargodha in its 1/2018 meeting held on 12-05-2018 has declared pharmaceutical industrial unit as research entity only, in order to provide strengthen the research activities at UOS. Now, as per decision of the Syndicate, the above Industrial Unit will be used only as "Research and Training Unit" for pharmacy students and researchers, as well as other integrated disciplines. This pharmaceutical industrial unit will not be run for commercial purposes. He has submitted as under:-

a. This is for your kind information and subsequent necessary action in this regard please.
b. He has requested to facilitate in this regard according to the law and licensing terms to run above unit as research and training only.

It is pertinent to mentioned that UOS Pharmaceutical Laboratories, Sarghoda was granted registration in 273rd meeting and registration letters were issued as per following details:-

S.No.	Reg. No.	Name of Drug(s) & Composition	Packing	MRP
1.	086170	Reinolex 250mg Tablet Each film coated tablet contains: Ciprofloxacin as hydrochloride …….250mg (BP Specifications)	10's	Rs.130/-
2.	086171	Reinolex 500mg Tablet Each film coated tablet contains: Ciprofloxacin as hydrochloride ……500mg (BP Specifications)	10's	Rs.215/-
3.	086172	Sarmed 50mg Tablet Each enteric coated tablet contains: Diclofenac sodium…….50mg (USP Specifications)	20's	Rs.60/-

4.	086173	Sarflam 50mg Tablet Each film coated tablet contains: Diclofenac potassium…….50mg (USP Specifications)	20’s	Rs.60/-
5.	086174	Accflam 100mg Tablet Each film coated tablet contains: Aceclofenac……..100mg (As per *Innovator’s Specifications)	10’s	Rs.75/-
6.	086175	Zyrtezine 10mg Tablet Each film coated tablet contains: Cetirizine hydrochloride ……..10mg (USP Specifications)	10’s	Rs.42/-
7.	086176	Spondulac-B 20mg Tablet Each tablet contains: Piroxicam β cyclodextrin equivalent to piroxicam...20mg (As per Innovator’s Specifications)	20's	Rs.175/-
8.	086177	Omepasec 20mg Capsule Each capsule contains: Omeprazole enteric coated pellets eq.to Omeprazole .....20mg (BP Specifications)	14's	Rs.144/-
9.	086178	Omepasec 40mg Capsule Each capsule contains: Omeprazole enteric coated pellets equivalent to omeprazole…….40mg (BP Specifications)	2x7’s	Rs.250/-
10.	086179	Benzipep 20mg Capsule Each capsule contains: Esomeprazole enteric coated pellets equivalent to esomeprazole…….20mg (USP Specifications)	2x7's	Rs.119/-
11.	086180	Benzipep 40mg Capsule Each capsule contains: Esomeprazole enteric coated pellets equivalent to esomeprazole…….40mg (USP Specifications)	2x7's	Rs.198/-
12.	086181	Spondulac 20mg Capsule Each capsule contains: Piroxicam ……20mg (USP Specifications)	10’s	Rs.71/-
13.	086182	Nexafib 250mg Capsule Each capsule contains: Tranexamic acid……..250mg (JP Specifications)	100's	Rs.650/-
14.	086183	Sarmed 100mg Capsule Each capsule contains: Diclofenac sodium enteric coated pellets equivalent to Diclofenac sodium…….100mg (As per Innovator’s Specifications)	30’s	Rs.138/-
15.	086184	Leishnil 50mg Capsule Each capsule contains: Miltefosine……50mg (As per *Innovator’s Specifications)	56's	Rs.16,000/-

16.	086185	Nomalus Dry Suspension After reconstitution each 5ml contains: Artemether ……..15mg Lumefantrine……90mg (IP Specifications)	30ml	Rs.90/-
17.	086186	Histoplasmazole Dry Suspension After reconstitution each 5ml contains: Fluconazole……50mg (USP Specifications)	35ml	Rs.210/-
18.	086187	Olizid Dry Suspension After reconstitution each 5ml contains: Linezolid……100mg (As per Innovator's Specifications)	60ml	Rs.350/-
19.	086188	Macclar 125mg Dry Suspension After reconstitution each 5ml contains: Clarithromycin taste masked granules …125mg (USP Specifications)	60ml	Rs.223/-
20.	086189	Macclar 250mg Dry Suspension After reconstitution each 5ml contains: Clarithromycin taste masked granules …250mg (USP Specifications)	60ml	Rs.368/-
21.	086190	Dimune-Z Oral Syrup Each 5ml contains: Zinc sulphate eq. to elemental Zinc……20mg (USP Specifications)	60ml	Rs.60/-
22.	086191	Navostatin Oral Suspension Each 1ml contains: Nystatin……100000 IU (USP Specifications)	30ml	Rs.48/-
23.	086192	Zyrtezine Oral syrup Each 5ml contains: Cetirizine hydrochloride …….5mg (USP Specifications)	60ml	Rs.27/-
24.	092114	Contaflex 250mg Tablet Each film coated tablet contains: Levofloxacin hemihydrate eq. to Levofloxacin…250mg (USP Specifications)	10's	Rs.250/-
25.	092115	Contaflex 500mg Tablet Each film coated tablet contains: Levofloxacin hemihydrate eq.to Levofloxacin...500mg (USP Specifications)	10's	Rs.416/-
26.	092116	Firmivit-F 100mg Tablet Each tablet contains: Iron III hydroxide polymaltose complex equivalent to elemental iron ……100mg Folic acid…….0.35mg (As per * innovator's Specifications)	2x10's	Rs.95/-
27.	092117	Histoplasmazole 150mg Capsule Each capsule contains: Fluconazole….150mg (BP Specifications)	1's	Rs.138/-

Decision: **Keeping in view the decision of Central Licensing Board for cancellation of Drug Manufacturing License the Registration Board deliberated and cancelled the registrations of all drug products registered in the name of M/s UOS Pharmaceutical Laboratories, University of Sargodha.**

Case No.38: Pending Registration cases of M/s. Moringa Pharmaceuticals (Pvt.) Ltd. Lahore.

The Registration Board in its 237th meeting decided the following registration applications of M/s. Moringa Pharmaceuticals (Pvt.) Ltd. Lahore. The details is as under:-

S. No.	Name of firm(s)	Name of Drug(s) with formulation	Applied pack size	Applied MRP	Date of Submission	Decision of RB
1.	M/s. Moringa Pharmaceuticals (Pvt.) Ltd. Lahore New License Sections (i) Tablets (ii) Capsules (iii) Dry powder Suspension (iv) Liquid syrup.	Gabafit Capsules 150mg Each capsule contains:- Pregabalin…150mg (Anticonvulsant)	2×7's	Rs.350.00	22-1-2013	Deferred
2.	-do-	Gabafit Capsules 75 mg Each capsule contains:- Pregabalin…..75mg (Anticonvulsant)	1x14's	Rs.237.00	-do-	Deferred for review.
3.	-do-	Omefix-20 Capsules 20/1100 Each capsule contains:- Omeprazole…20mg Sodium Bicarbonate…1100mg (PPI & antacid)	2×7's	Rs.146.00	-do-	Deferred
4.	-do-	Omefix-40 Capsules 40/1100 Each capsule contains:- Omeprazole…40mg Sodium Bicarbonate…1100mg (PPI & antacid)	2×7's	Rs.252.00	-do-	Deferred
5.	-do-	Winpain Tablets 550mg Each film coated tablet contains:- Naproxen Sodium…550mg (NSAID)	1×20's	Rs.198.00	-do-	Approved.
6.	-do-	Fexal-120mg Tablets Each film coated tablet contains: Fexofenadine HCl…….120mg (antihistamine)	*10's*	Rs.120.00	-do-	Approved.
7.	-do-	Fexal-180mg Tablets Each film coated tablet contains:- Fexofenadine HCl…….180mg (antihistamine)	10's	Rs.169.00	-do-	Approved.
8.	-do-	Methicol Tablet 500mcg Each sugar coated tablet contains Mecobalamin…..500mcg (vitamin, endogenous coenzyme B12)	3x10's	Rs.255.00	-do-	Approved.

The firm has again submitted application dossiers on Form-5 alongwith attested copy of challan from treasury officer, Lahore of Rs. 1,60,000/-. GMP inspection of firm was conducted on 06-06-2018 reflecting that firm do have Tablet (General & Antibiotic) and Capsules (General & Antibiotics) sections. Firm has requested to issue the registration of above products.

Decision: Registration Board decided to approve the above-mentioned products in the name of M/s M/s. Moringa Pharmaceuticals (Pvt.) Ltd. Lahore.

VETERINARY CASES

Case No.39: M/s. Noble Pharmaceuticals, Old Industrial Area, Mirpur, AJK.

QA&LT Division of DRAP, Islamabad has forwarded the case of M/s. Noble Pharma, Mirpur Azad Kashmir that Federal Inspector of Drugs-III, Islamabad performed routine GMP inspection of M/s. Noble Pharma, Mirpur Azad Kashmir on 16-11-2018 wherein it has been observed that the firm has following two registered penicillin containing products but has no separate penicillin manufacturing section (veterinary).

S.No	Reg. No.	Name of drug(s) & Composition.
1.	058725	Nobi-PSBC Powder Each 1000gm contains:- Procain Penicillin……12gm Streptomycin Sulpahte……36gm Zinc Bacitracin…….52gm Colistin Sulpahte……..60IU
2.	071009	Nobimox Powder Each Kg contains:- Amoxycillin Trihydrate….150gm Colistine Sulphate…..…..50 M.I.U

Decision:- Registration Board decided to issue show cause notice to M/s. Noble Pharma, Mirpur Azad Kashmir for cancellation of registration of above mentioned products registered in the name of M/s. Noble Pharma, Mirpur Azad Kashmir for not possessing the penicillin manufacturing facility.

Case No. 40: Request of M/s. Orient Traders International, Karachi for Grant of Additional Pack Size for Already Registered Veterinary Drug.

M/s. Orient Traders International, Karachi has requested for grant of additional pack size for their following registered imported veterinary product. Details are mentioned below;

S. #	Reg. No.	Name of Drug (s) / Composition.	Existing Pack.	Demanded Additional packs.	Initial Date of Regn. Letter	Justification
1.	093614	Lincomycin-40S Oral Powder Each gm contains:- Lincomycin Hydrochloride equivalent to Lincomycin…..400mg	100gm 500gm 1Kg 10Kg 25Kg	1.5Kg	25th January, 2019	*"Will be more feasible to farmer with respect to its cost & usage".*

M/s. Orient Traders International, Karachi has deposited fee of Rs.5000/- and submitted required supporting documents including;

(i) Copy of initial Registration letter.
(ii) Copy of Drug Sale License.
(iii) Copy of free sale certificate issued by Belgium authorities wherein the demanded pack size is mentioned as "***Plastic jar of 1.5kg***. Original of the same free sale certificate is already present/submitted at the time of processing of registration letter (issued dated 24-10-2018).

The demanded pack is not given to other firms.

Decision:- Registration Board approved the grant of additional pack size of "*1.5 Kg plastic jar*" to registered product Lincomycin-40S Oral Powder (Reg.No. 093614) of M/s. Orient Traders International, Karachi on same terms and conditions.

Case No. 41: Request of M/s. Elko Organization (Pvt) Ltd., Karachi for Grant of Additional Packs for their already Registered Veterinary Drugs.

M/s. Elko Organization (Pvt) Ltd., Karachi has applied for grant of additional pack sizes of their following registered veterinary drugs as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	071043	Elcoamax Oral Powder Each 100gm contains:- Amoxicillin (as Sodium)...10gm Colistin Sulphate…..50 MIU	100gm 500gm 1000gm	2.5 Kg	28-06-2011 03-06-2016	"*to facilitate the farmer, as they demand large quantity pack*".
2.	026536	Elkoloc Powder Each 125gm contains:- Sulphabenzpyrine...25000mg 2.4-diamino-5 Veratrylpyrimidine…6250mg Menadione Sulphate Sodium (K3)…….625mg	250gm 500gm 1000gm	2.5 Kg	13-06-2001 03-06-2016	-do-

M/s. Elko Organization (Pvt) Ltd., Karachi has deposited the required fee of Rs.5,000 x 2 = Rs. 10,000/- and submitted following supporting documents:-

(i) Copies of initial registration letters and latest renewal status.
(ii) Undertaking that the provided information/documents are true/correct.
(iii) Copy of GMP inspection report conducted by area FID on 25-03-2019.

The demanded packs are not given to other firms.

Decision: Registration Board approved the grant of following additional pack sizes to registered products of M/s. Elko Organization (Pvt) Ltd., Karachi on same terms and conditions.;

S.No.	Regn. No.	Name of Drug(s)/Composition	Approved Additional Pack(s)
1.	**071043**	**Elcoamax Oral Powder** **Each 100gm contains:-** **Amoxicillin (as Sodium)…10gm** **Colistin Sulphate…..50 MIU**	**2.5 Kg**
2.	**026536**	**Elkoloc Powder** **Each 125gm contains:-** **Sulphabenzpyrine...25000mg** **2.4-diamino-5 Veratrylpyrimidine…6250mg** **Menadione Sulphate Sodium (K3)…625mg**	**2.5 Kg**

Case No. 42: Request of M/s. Leads Pharma, Islamabad for Grant of Additional Pack Sizes For Already Registered Veterinary Drugs.

M/s. Leads Pharma, Islamabad has applied for approval of additional packs of their registered veterinary drugs as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	082801	Combipen Injection Each ml contains:- Benzathine Penicillin G.100,000 IU Procaine Penicillin G….150,000 IU Dihydrostreptomycin Sulphate ……..200.00mg (As per Innovator's Specification*)	50ml	100ml	31st October, 2017	*Demanded by the veterinary prescribers and marketing due to economical for the farmer to purchase.*

2.	082802	Lemoxil 15% Injection Each ml contains:- Amoxicillin Trihydrate equal to Amoxicillin base……..150mg (As per Innovator's Specification*)	50ml	100ml	31st October, 2017	-do-
3.	082797	Amcocin Injection Each ml contains:- Amoxicillin Trihydrate…….100mg eq.to 86.96mg Amoxicillin base Colistin Sulphate …250,000 IU (As per Innovator's Specification*)	50ml	100ml	31st October, 2017	-do-
4.	082798	Ledomentan Injection Each ml contains:- Amoxicillin (as Trihydrate)..140mg Clavulanic acid (as Potassium Clavulanate) USP……35mg (As per Innovator's Specification*)	50ml	100ml	31st October, 2017	-do-
5.	082800	Ampileads Injection Each ml contains:- Ampicillin Trihydrate…200mg (As per Innovator's Specification*)	50ml	100ml	31st October, 2017	-do-

M/s. Leads Pharma, Islamabad has deposited the required fee of Rs.5,000x5=Rs. 25,000/- and submitted following supporting documents:-

(i) Copies of registration letters.
(ii) Justification for additional packs.
(iii) Approved additional sections.
(iv) Approval for change of technical staff.
(v) Copy of Drug Manufacturing License.
(i) Copy of CRF.
(ii) Copy of latest GMP inspection report.
(iii) Certificate of GMP.

All the demanded additional pack sizes are for injection dosage form. As per current practice, separate registration number is given to different volumes of injectables, as quantity of drug /API changes with the change in total volume of pack / container.

Registration Board in its 282nd meeting decided to refer the case to Expert Working Group on Veterinary Drugs for further deliberation and their recommendations on the matter.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018 wherein it has been decided as follow;

"The Expert Working Group observed that as per guidelines / practice of Registration Board for giving separate registration to different volumes of injectables, the additional packs cannot be recommended. Moreover, the valid justification for the demand of the additional packs in higher volume is also required."

Decision:- Keeping in view the decision of the Expert Working Group on veterinary drugs, Registration Board did not acceded to firm's request for grant of additional pack size for their registered injection products.

Case No.43: Request of M/s. Decent Pharma, Rawat, Islamabad for Grant of Additional Pack Sizes For Already Registered Veterinary Drugs.

M/s. Decent Pharma, Rawat, Islamabad has applied for approval of additional packs of their registered veterinary drugs as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	084931	Suldin Injection Each ml contains:- Sulphadimidine Sodium (B.P)…….333mg (As per Innovator's Specification*)	500ml vial	100ml	18-08-2017	For household livestock's population small packing is required to avoid wastage i.e. cow, buffalo, sheep and goat.
2.	079171	Tide Injection Each ml contains:- Tylosin Tartrate…….50mg Colistin Sulphate……10mg Streptomycin……100mg	100ml	50ml	21-08-2015	-do-
3.	079168	Titan Injection Each ml contains:- Tylosin (as tartrate) B.P.100mg Gentamycin (as sulphate) B.P. ……50mg	100ml	50ml	21-08-2015	-do-
4.	079167	Combi-4 Injection Each ml contains:- Tylosin tartrate B.P..150mg Gentamycin sulphate B.P….60mg Chlorpheniramine….7.5mg Dexamethasone…..2.65mg	100ml	10ml 50ml	21-08-2015	-do-
5.	079164	Wagenta 100 Injection Each ml contains:- Gentamycin (as Sulphate) B.P 100mg	100ml	50ml	21-08-2015	-do-
6.	079165	Diatril Injection Each ml contains:- Enrofloxacin……100mg	100ml	10ml 50ml	21-08-2015	-do-
7.	079169	Bovex Injection Each ml contains:- Ivermectin……10mg Vitamin A……25000IU Vitamin D3…….3750IU Vitamin E…….25mg	50ml	10ml 100ml	21-08-2015	-do-
8.	079170	Ectin-C Injection Each ml contains:- Ivermectin……...10mg Closental……...125mg	100ml	10ml 50ml	21-08-2015	-do-
9.	081716	Spel Injection Each ml contains:- Spectinomycin (as sulphate).....100mg Lincomycin (as HCL)……50mg (Manufacturer Specification)	100ml	50ml	06-10-2016	-do-

M/s. Decent Pharma, Rawat, Islamabad has deposited the required fee of Rs.5,000 x 13 = Rs. 65,000/- and submitted following supporting documents:-

(i) Copies of registration letters.
(ii) Justification for additional packs.
(iii) Copy of CRF provided.

The case was considered in 8th PRVC meeting and it was decided to place the case for consideration of Registration Board as the demanded additional pack sizes are for injection dosage form. As per current practice separate registration number is given to different volumes of injectables, as quantity of drug /API changes with the change in total volume of pack / container.

Registration Board in its 282nd meeting decided to refer the case to Expert Working Group on Veterinary Drugs for further deliberation and their recommendations on the matter.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018 wherein it has been decided as follow;

The Expert Working Group observed that as per guidelines / practice of Registration Board for giving separate registration to different volumes of injectables, the additional packs cannot be recommended. However, the demanded packs, which are smaller than the existing ones and meant for household livestock population, can be considered for products mentioned at Sr. No. 1-3, 5,6, 8&9 of above table, if separate applications are filed in line with practice of giving separate registration to different volume of injectables. The products mentioned at Sr. No 4 & 7 of above table are recommended to be deferred for review of formulation.

Decision:- Keeping in view the decision of the Expert Working Group on veterinary drugs, Registration Board did not acceded to firm's request for grant of additional pack size for their registered injection products.

Case No.44: Request of M/s. Bio-Labs (Pvt) Ltd., Islamabad for Grant of Additional Pack Sizes For Already Registered Veterinary Drugs.

M/s. Bio-Labs (Pvt) Ltd., Islamabad has applied for approval of additional packs of their registered veterinary drug as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/Composition	Already Granted Pack Size(s)	Demanded Additional Pack(s)	Justification
1.	048122	Lions-Mox-C Water Soluble Powder Each 100gm contains:- Amoxycillin Trihydrate equivalent to Amoxycillin base……..15gm Colistin Sulphate……50 MIU	100gm 250gm 500gm 1000gm	1.5 Kg 5 Kg	*Due to market demand of additional pack.*
2.	046568	Biotil Liquid Each ml contains:- Tilmicosin (as Phosphate)…..250mg	60ml 250ml 500ml 1000ml	5 Litre	-do-

M/s. Bio-Labs (Pvt) Ltd., Islamabad has deposited the required fee of Rs.5,000 x 3 = Rs.15,000/- and submitted following supporting documents:-

(i) Copies of registration letters.
(ii) Renewal status of drugs.
(iii) Copy of Drug Manufacturing License.
(iv) Copy of approved section.
(v) Copy of CRF.

(vi) Copy of inspection report.

The demanded packs are not given to other firms.

Registration Board in its 283rd meeting decided to referred the case to Expert Working Group on Veterinary drugs for further consideration.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018 wherein it has been decided as follow;

The Expert Working Group recommended for grant of additional packs demanded by the firm as mentioned in above table with exception of 1.5kg of Lions-Mox-C Water Soluble Powder which is not recommended for having no rational justification.

Decision:- Keeping in view the decision of Expert working group on veterinary drugs, Registration Board decided as follow;

a. **Approved the grant of additional pack size of "*5 Kg and 5 liters*" for registered products Lions-Mox-C Water Soluble Powder (Reg.No. 048122) and Biotil Liquid (Reg.No. 046568) on same terms and conditions respectively.**
b. **Did not acceded to the request of firm for the grant of additional pack size of *1.5 Kg* for product Lions-Mox-C Water Soluble Powder (Reg.No. 048122) by the firm having no rational justification.**

Case No.45: Request of M/s. Nawan Laboratories (Pvt) Ltd., Karachi for Grant of Additional Packs for their already Registered Veterinary Drugs.

M/s. Nawan Laboratories (Pvt) Ltd., Karachi has applied for grant of additional packs of their following registered veterinary drugs as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/ Composition (as per initial registration letter)	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	035063	ADE Minerals Each kg contains:- Vitamin A……0.5MU Vitamin D…….0.080MU Vitamin E……..0.300gm Calcium…….225.0gm Phosphorous.….120.0gm Magnesium…….25.0gm Sodium……....20.0gm Iron (as Ferrous)....1.0gm Zinc……3.0gm Manganese……...2.0gm Copper……...0.600gm Cobalt ……0.010gm Iodine……....0.020gm Selenium ……...0.003gm	1Kg 5Kg	25Kg	13-12-2004 10-12-2014	• Marketing demand. • Customer convenience. • Economical, easier to administration and affordable for farmers, suppliers and customers.
2.	021306	L.S. Minerals Powder Each kg contains: - Calcium……155gm Phosphorous…….135gm Magnesium……55gm Sodium……....45gm Iron (as Ferrous)….1gm Zinc…….3gm Maganese……...2gm Copper…….0.6gm	1Kg 5Kg	25Kg	11-05-1998 08-05-2018	-do-

		Cobalt……..…0.01gm Iodine…….0.04gm Selenium……...0.003gm				

M/s. Nawan Laboratories (Pvt) Ltd., Karachi has deposited the required fee of Rs.5,000x2 = Rs. 10,000/- and submitted following supporting documents:-

(i) Attested copies of initial registration letters and latest renewal status..
(ii) Details of previously granted pack size.
(iii) Undertaking that the provided information/documents are true/correct.
(iv) GMP inspection conducted by DRAP during last 12 months.
(v) Attested copy of Drug Manufacturing License.
(vi) Attested copy of CRF provided.
(vii) Justification of proposed change.

The demanded packs are not given to other firms.

Registration Board in its 286th meeting decided to refer the case to Expert Working Group on Veterinary Drugs for their recommendations on demanded additional pack sizes.

The case was accordingly discussed in 6th meeting of Expert Working Group on Veterinary Drugs held on 20th March, 2019 and the working group decided as follow;

"Keeping in view the need of packing in large size farms, recommended the grant of additional pack of 25Kg for above mentioned products demanded by the firm."

Decision:- Registration Board deferred the case for obtaining details from the firm regarding facility/equipments w.r.t their capacity of mixing/ preparation/ filling of demanded pack sizes.

Case No. 46: Request of M/s. Hilton Pharma (Pvt) Ltd., Karachi for Grant of Additional Packs for their already Registered Veterinary Drugs.

M/s. Hilton Pharma (Pvt) Ltd., Karachi has applied for grant of additional packs of their following registered veterinary drugs as per details mentioned against each:-

S.No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	044909	Hicos 250 Oral Solution Each ml contains:- Tilmicosin…….250mg	60ml 450ml 1 Litre 3 Litre	5 Litre 10 Litre 15 Litre	25-01-2007 23-11-2016	*Due to market needs and cost effectiveness.*
2.	026467	Beloran Disinfectant Solution Each 1000ml contains:- Benzalkonium Chloride 50% Solution……800gm	1000ml	5 Litre 10 Litre 25 Litre	24-02-2001 02-09-2015	*-do-*

M/s. Hilton Pharma (Pvt) Ltd., Karachi has deposited the required fee of Rs.5000 x 6 = Rs. 30,000/- and submitted following supporting documents:-

(i) Copies of initial registration letters.
(ii) Renewal status.
(iii) Copy of additional packs already granted.
(iv) Justification for approval of additional packs.
(v) Undertaking.
(vi) GMP inspection conducted by DRAP conducted on 17-07-2018.

The demanded packs are not given to other firms.

Decision:- **Registration Board decided as follow:**

a. **Approved the grant of additional pack sizes of *5 liter, 10 liter and 15 liter* to registered product Hicos 250 Oral Solution (Reg.No. 044909) on same terms and conditions.**
b. **Deferred the case for product at Sr.No.2 for review of the product/molecule by expert working group on veterinary drugs.**

Case No. 47: **Request of M/s. U.M. Enterprises, Karachi for Grant of Additional Pack Sizes for Already Registered Veterinary Drug.**

M/s. U.M. Enterprises, Karachi has requested for grant of additional pack sizes for their following registered veterinary product. Details are mentioned alongside.

S. #	Reg. No.	Name of Drug (s) / Composition.	Existing Pack.	Demanded Additional packs.	Initial Date of Regn. Letter/ Dairy No. & Date	Justification
1.	088152	Diclacox Liquid Each ml contains:- Diclazuril……10mg	500ml plastic bottle	1 Litre plastic bottle	08th March, 2018 Dy.No. 4037 (R&I) DRAP Dated 19-04-2019	Due to customers/ consumers. Larger pack sizes are more suitable for large farmers"

M/s. U.M. Enterprises, Karachi has deposited the required fee of Rs.5000/- and submitted required supporting documents including;

(i) Copy of initial Registration letters..
(ii) Copy of Drug Sale License.
(iii) Original legalized free sale Certificate (alongwith approval of the pack sizes) issued by Regulatory Authority of Exporting Country i.e. Jordan.
(iv) Justification.
(v) Label.
(vi) Undertaking.

The demanded packs are not given to other firms.

Decision:- **Registration Board approved the grant of additional pack size of "*1 liter plastic bottle*" for registered product Diclacox Liquid (Reg.No. 088152) of M/s. U.M. Enterprises, Karachi on same terms and conditions.**

Case.No.47: **M/s. Attabak Pharmaceuticals, Islamabad.**

Federal Inspector of Drugs-IV, Islamabad has informed that a routine GMP inspection of M/s. Attabak Pharmaceuticals, Islamabad was conducted on 29-06-2018 wherein it has been observed that the firm has seven registered penicillin products but has no separate penicillin manufacturing section. The Federal Inspector of Drugs further informed that at present lay out has been approved for new penicillin section. Federal inspector of Drugs has provided the following list of registered products having penicillin of M/s. Attabak Pharmaceuticals alongwith registration letters.

S. No.	Regn. No.	Name of Drug(s)/Composition
1.	063822	Salinobak Water Soluble Powder Each 100gm contains:- Lincomycin as Hcl ……. 5.0gm Spectinomycin as Hcl ……..5.0gm Amoxicillin Trihydrate ……10gm
2.	069629	Amoxibak LA Injection. Each ml contains:- Amoxicillin as Trihydrate 15% w/v

3.	071053	Moxin-L Water Soluble Powder Each 100gm contains:- Lincomycin as HCl ……5gm ColistinSulphate….. ….50MIU Amoxicillin Trihydrate ….10gm BromhexineHCl …….0.5gm
4.	071054	Amox-C Maarson Powder Each 100gm contains:- Amoxicillin as Trihydrate…50gm ColistinSulphate … …….50MIU
5.	071061	Amoxibak Water Soluble Powder Each 100gm contains:- Amoxicillin as Trihydrate…15gm Colistinsulphate ……50MIU
6.	071062	Amoxitin-C Water Soluble Powder Each 100gm contains:- Amoxicillin as Trihydrate…20gm Colistinsulphate …….. 80MIU
7.	071063	As-Plus Water Soluble Powder. Each 100gm contains:- Spectinomycin as HCl …. 5.0gm ColistinSulphate ……50MIU Amoxicillin Trihydrate .….10gm BromhexineHCl ……. 0.5gm

With reference to product at Sr. No.1 it is submitted that the product has already been transferred to M/s. D-Maarson Pharmaceuticals, Rawat, Rawalpindi.

Registration Board in its 286th meeting decided to issue show cause notice to M/s. Attabak Pharmaceuticals, Islamabad for cancellation/suspension of registration of above mentioned products registered in the name of M/s. Attabak Pharmaceuticals, Islamabad for not possessing the penicillin manufacturing facility.

Show cause notice issued to M/s. Attabak Pharmaceuticals, Islamabad. In response the firms informed as under:-

(i) We would like to inform you that our sections are ready for inspection and we informed to Assistant Director (Licensing) dated 4-1-2019.

(ii) Licensing Department has constituted a panel for inspection of our penicillin section dated 25th February, 2019.

The firm has requested to withdraw the show cause notice in the greater interest of justice.

Decision:- Registration Board deferred the case for obtaining details from Licensing Division of DRAP regarding the updated status of firm's penicillin section.

Case.No.48:- Registration of Drugs under the Drugs Act, 1976.

Registration Board in its 239th meeting held on 12th September, 2013 deferred the following drugs of M/s. Medi-Vet (Pvt) Limited, Lahore due to stoppage of production by Central Licensing Board.

S. #	Name of Drug(s)/Composition	Pack Size	Shelf Life	Registration Board Decision
1.	Floxivet-C Injection Each ml contains:- Enrofloxacin B.P Vet.….100mg/ml Colistin Sulphate BP..250000 iu/ml (Antibiotic/Antibacterial).	100ml 250ml 500ml 1000ml	02 years	Deferred as production of firm has been stopped by CLB

2.	Medi-Voc Injection Each ml contains:- Ivermectin B.P……...10mg (Dewormer/ Anthelmintic).	100ml 250ml 500ml 1000ml	02 years	-do-

The firm has now provided copy of letter issued by Secretary CLB, dated 29-01-2019, wherein it has been mentioned that "*on the recommendations of the panel of experts, the Central Licensing Board in its 267th meeting held on 31-12-2018 has considered and approved the resumption of the production in the following one (1) section (Liquid Injectable Veterinary Section) of your firm M/s. Medivet (Pvt) Ltd, 16-Km, Sheikhupura Road, Lahore under Drug Manufacturing License No.000269 (Formulation)*"

Decision:- **Registration Board decided as follow;**

a. Keeping in view the resumption of production of Liquid injectable veterinary section of M/s. Medi-vet (Pvt) Ltd, 16 Km, Sheikhupura Road Lahore (DML No.000269) by the Central Licensing Board , Registration Board approved the product *Medi-Voc Injection* as per details mentioned below. Furthermore, the firm shall select one pack size among the demanded pack sizes before issuance of Registration letter.

S. #	Name of Drug(s)/ Composition	Pack Size	Shelf Life	Finished product Specification
1.	**Medi-Voc Injection Each ml contains:- Ivermectin……...10mg**	**100ml 250ml 500ml 1000ml**	**02 years**	**BP specification**

b. Deferred the product *Floxivet-C Injection* for confirmation of me-too status.

Case No. 49: Request of M/s. Leads Pharma (Pvt) Ltd Islamabad for Correction of Pack Sizes.

Registration Board in its 282nd meeting approved following veterinary drug of M/s. Leads Pharma (Pvt.) Ltd, Islamabad. However, further processing of the registration letter of following product was withheld for getting clarification regarding approved pack size.

S. No	Name of Manufacturer	Name of drug(s) & Composition	Approved Packs Size(s)	Remarks
1.	M/s. Leads Pharma (Pvt.) Ltd, 81-A, Street No. 06, I-10/3, Islamabad.	Doxyfas-50 Powder Each 1Kg contains:- Doxycycline HCl…500g	10 ml x 5's vial	Approved with innovator's specification.

From original dossier it has been checked that in Form-5 submitted by the firm with registration application, the demanded pack sizes are mentioned as 100gm, 250gm,500gm, 1Kg, 2.5Kg & 5Kg while the pack size "10ml x 5's vial" has been mentioned inadvertently in minutes. The firm has requested for correction of pack sizes in minutes of the meeting.

Decision:- **Registration Board approved the correction in minutes w.r.t pack size of approved product Doxyfas-50 Powder from "*10 ml x 5's vial*" to "*100gm, 250gm,500gm, 1Kg, 2.5Kg & 5Kg*.**

Case No. 50:- **Show Cause Notices issued to the firms having registration of products containing Norfloxacin.**

Registration Board in its 249th meeting while rejecting applications of veterinary drugs containing Norfloxacin due to development of resistance in human the Board also decided to issue show cause notice to already registered products for cancellation. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The salient points, of the responses received are summarized as under:-

i) The drug is considered vital to combat stubborn bacterial infections faced by the poultry section.
ii) No scientific approval information regarding Norfloxacin resistance in human.
iii) Extensive study needs to be carried out before making a decision on this issue.
iv) Under Section 7 (11) of Drugs Act, 1976, detail of the information or enquiry conducted, on the basis of which the decision was taken, may be communicated for response.
v) The drug has no significant residual effect on human body.
vi) A few firms also agreed to withdraw the products.
vii) A number of the firm requested for opportunity for personal hearing.

The Board in 262nd meeting referred the case to Dr. Qurban Ali for further evaluation and recommendations. Dr. Qurban Ali in 265th meeting informed the Board that the case is under study for developing policy recommendations. The Board accordingly deferred the case in 265th and subsequent meetings.

The case was again discussed in 278th meeting decided that Dr. Qurban Ali, Member Registration Board informed that he will submit report after reviewing all relevant references and literature.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018wherein it has been decided as follow;

"The Group observed that Ciprofloxacin has already been banned for veterinary use so two antibiotics of Quinolone group i.e. Enrofloxacin and Norfloxacin may continue to be permitted for having more choice for controlling infections in veterinary practices".

Decision:- **Registration Board deferred the case for further deliberation on the matter in light of status in reference regulatory authorities.**

Case No.51:- **Show Cause Notices issued to the firms having registration of products containing Phenylbutazone.**

Registration Board in its 260th meeting while rejecting applications of veterinary drugs containing Phenylbutazone as drug is not recommended for use in food producing animals the Board also decided to issue show cause notices to all registered veterinary drug formulation containing Phenylbutazone. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The salient points, of the responses received are summarized as under:-

i) The drug is used in equines like horse, donkeys etc. which is not meant for human consumption, therefore there is no problem of residual effect
ii) Extensive study needs to carry out before making a decision on this issue.

iii) Under Section 7 (11) of Drugs Act, 1976, detail of the information or enquiry conducted, on the basis of which the decision was taken, may be communicated for response.

iv) A few firms also agreed to withdraw the products

The Board in 262nd meeting referred the case to Dr. Qurban Ali for further evaluation and recommendations. Dr. Qurban Ali in 265th meeting informed the Board that the case is under study for developing policy recommendations. The Board accordingly deferred the case in 265th and subsequent meetings.

The case was again discussed in 278th meeting decided that Dr. Qurban Ali, Member Registration Board informed that he will submit report after reviewing all relevant references and literature.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018wherein it has been decided as follow;

"The Group, after deliberation, observed that since the Phenylbutazone is primarily used in equine animals so its use should be restricted to these animals only. Moreover, prominent warning on label of drugs containing Phenylbutazone, restricting its use in nonfood producing animals, should also appear in conspicuous manner."

Decision:- Registration Board deferred the case for further deliberation on the matter in light of status in reference regulatory authorities.

Case No.52:- Show cause notices issued to firms having registration of products containing Amantadine in combination with other antibiotics/ antibacterial.

Registration Board in its 249th meeting decided to issue show cause notices for cancellation of all the drug formulations having Amantadine in combination with antibiotic/ antibacterials for veterinary use for having drug interaction and resistance problem. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The case was placed before the Registration Board in its 257th meeting and the Board directed to place comments of all firms / stake holders before the Board in its next meeting. Accordingly, the responses of the firms were placed before the Board in 258th meeting. The salient points, of the responses received are summarized as under:-

i) Huge financial losses to the firms /distributor as heavy investment have been made in the products.
ii) No complaints/information regarding interaction of Amantadine with antibiotic/ antibacterial, is reported.
iii) These combinations play very important role for treatment of diseases like Bird flu, Influenza.
iv) Extensive study needs to be carried out before making a decision on this issue.
v) Under Section 7 (11) of Drugs Act, 1976, detail of the information or enquiry conducted, on the basis of which the decision was taken, may be communicated for response.
vi) A few firms also agreed to withdraw the products and requested for grant of registration of other products instead.
vii) A number of the firm requested for opportunity for personal hearing.
viii) Pakistan Poultry Association has claimed that Amantadine based products are effective and safe for veterinary practices, that they have not received any complaint. The Association has requested for withdraw of the decision.

ix) Pakistan Veterinary Pharmaceutical Association has claimed that Amantadine based products are effective and safe for veterinary practices and they have received no complaint regarding such products. The Association has requested for withdrawal the decision.

Registration Board deferred the case in its 258th meeting due to paucity of time and took it again in 259th meeting. The following decision was taken.

Registration Board referred the matter to Dr. Muhammad Arshad, Member Registration Board, for giving his detail views (approval status of products by reference regulatory authorities, pharmacological and pharmaceutical compatibility etc) on the matter after consultation with other concerned experts in veterinary field.

Since no response was received from Dr. Muhammad Arshad so the Registration Board in its 262nd meeting decided to refer the matter to Dr. Qurban Ali, Director General, National Veterinary Laboratory, Islamabad/ Member Registration Board for expert views.

The Board in 262nd meeting referred the case to Dr. Qurban Ali for further evaluation and recommendations. Dr. Qurban Ali in 265th meeting informed the Board that the case is under study for developing policy recommendations.

The case was again discussed in 278th meeting decided that Dr. Qurban Ali, Member Registration Board informed that he will submit report after reviewing all relevant references and literature.

The case was accordingly discussed in 5th meeting of Expert Working Group on Veterinary Drugs held on 27th December, 2018 wherein it has been decided as follow;

"The group deliberated the matter in depth and in absence of any recognized scientific rational, regarding simultaneous use of antibiotic with antiviral drugs, all such combination are recommended to be withdrawn."

Decision:- Registration Board deferred the case for further deliberation on the matter in light of status in reference regulatory authorities.

Case No. 53:- Complaint of M/s. Mehran International, Karachi Regarding Resemblance of Packaging.

M/s. Mehran International, Karachi has complaint that the label and box of registered product of M/s. International Pharma Labs., Lahore namely Gentamin 10% 100ml (Regn. No. 041238) has resemblance with the label and box of their registered product namely Gentamicin Injection 10% (Regn. No. 022179). The firm has informed that their product is registered earlier than the product of M/s. International Pharma Labs., Lahore.

As an evidence the firm has provided boxes of both products and requested that M/s. International Pharma Labs., Lahore may be advised to change the packing of the label and box of their product. In accordance with the decision of 2nd PRVC meetingM/s. International Pharma Labs., Lahore, which got the registration of product namely Gentamin 10% 100ml (Regn. No. 041238) later, was advised to change packaging design of their product under intimation to this office.

M/s. International Pharma Labs., Lahore in response submitted as under:-

- As you can see by yourself neither the picture of animals, nor the font & design is same.
- Company M/s. Mehran International allegation is baseless.
- As you can physically see our box is of white colour and there is snow white our box original pack is attach with.

- As urdu version of dosage and composition on above said Chinese product is not available and same is misbranded as defined in Drug Act, 1976 but urdu version according to law is available as on packing of International Pharma Labs., Lahore which is part of our design. So in the light of point discussed above our product design is totally different from them if your good self is not satisfied then give us a chance to justify our self personally.

The case was considered in 8th PRVC meeting and the Committee decided to place the case before Registration Board.Registration Board in its 282nd meeting decided to issue show cause notice to M/s. International Pharma Labs., Lahore for having resemblance of packaging design of their registered product with that of another registered product of M/s. Mehran International, Karachi.

Accordingly show cause notice was issued to M/s. International Pharma Labs., Lahore. In response the firm has informed that "*we are hereby ready to change the design and fount of our product required by your good self. The change design is attach with this letter please approve our design and make us to think you.*"

Decision:- **Registration Board noted and endorsed the changes made in packaging design and font by M/s. International Pharma Labs., Lahore for their registered product Gentamin 10% 100ml (Regn. No. 041238) on complaint of M/s. Mehran International, Karachi**.

Case No. 54:- **Request of M/s. Ani Cure Veterinary Services, Rawalpindi for change of address (local) for their registered products.**

M/s. Ani Cure Veterinary Services, Rawalpindi has requested for change of local address for their following registered products as per following details:-

S. No	Reg. No.	Name of Drugs/ Composition	Name & Address of importer (as per approval letter)	Name & Address of Importer (as per New DSL)
1.	022761	Flumesol-500 Oral Solution Each ml contains:- Flumequine..500mg	M/s. Ani Cure Veterinary Services, Office No.17, 2nd Floor, Kala Khan Shoping Centre. Shamsabad, Murree Road, Rawalpindi.	M/s. Ani Cure Veterinary Services, House No.B-1200, Block-B, Satellite Town, Rawalpindi.
2.	023449	Genta-100 Injectable Solution Each ml contains:- Gentamycin Sulfate eq. to 100mg Gentamycin base.	-do-	-do-
3.	023450	Limoxin-200 LA Injectable Solution Each ml contains:- Oxytetracyclinedihydrate eq. to 200mg oxytetracycline base.	-do-	-do-
4.	026544	Doxin-200 Water Soluble Powder Each gm contains:- Doxycycline Hyclate……..100mg Tylosin Tartrate…….100mg	-do-	-do-

Firm has deposited fee of Rs. 5000 x 4 = Rs.20,000/- and provided the following documents:-

(i) Copies of initial registration letters.
(ii) Copy of transfer of registration letter.

(iii) Copy of last renewal status.
(iv) Copy of Drug Sale License (new and old DSL)

Decision:- Registration Board approved the change in local address of importer M/s. Ani Cure Veterinary Services, Rawalpindi from "*M/s. Ani Cure Veterinary Services, Office No.17, 2nd Floor, Kala Khan Shoping Centre. Shamsabad, Murree Road, Rawalpindi"* to "*M/s. Ani Cure Veterinary Services, House No.B-1200, Block-B, Satellite Town, Rawalpindi*" in accordance with DSL for above mentioned products on same terms and conditions. Approval letter shall be issued after verification of storage facility of new site.

Case No.55:- 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) 2ml 50ml 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, InterchemieWerken) Me-too B.G. Oxy-50 Injection M/s. Biogen PharmaRawat.	i) Initial registration letter not provided. ii) The registration renewal letter (issued in 1985) does not contain detail. iii) Composition and renewal date in National Formulary of Pakistan the product appear as Oxytetracycl ine injection having composition each 2ml contains Oxytetracycl ine (as HCI) 50mg.	**i)**Initial registration certificate is not available at this time. **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. **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

					iv) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. v) Finished product specification not provided.	additional pack and new design/color scheme are attached for reference. **iv)**Form 5 dully signed by the contract giver/registration holder 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 18-07-2006 Renewal submitted 06-08-2011 (Last renewal application submission) 15-07-2016	a. Bimectin (Canada, Bimeda-MTC Animal Health Inc) 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/- **ii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **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. **ii)** Form 5 dully signed by the contract giver/registration holder provided. **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……0.382% w/v **(Composition as per initial registration letter)** 100ml 500ml	043507 18-07-2006 Last renewal application submission date 15-07-2016.	**a.** LevafasCluke and Worm (Drench. Rep. of Ireland. Norbrook Laboratorries (Ireland) Ltd.) **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/- **ii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **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. **ii)** Form 5 dully signed by the contract giver/registration holder provided. **iii)** Finished product

		1000ml 5000ml			**iv)** Latest inspection report of M/s. Intervac for Liquid Section. **v)** Master formula is not correct.	specification provided. **iv)** Latest inspection report of M/s. Intervac(Pvt) Ltd. For liquid section. **v)** Master formula of Levopower Drench provided.
4.	-do-	Levozide Solution Contains:- Levamisole HCI B.P. (Vet)……1.5 % w/v (Composition as per Form-5) 100ml 250ml 500ml 1 Litre	008038 27-02-1985 Already renewed upto 26-02-2015. Last renewal application submitted on 10-02-2015.	a. Chanaverm Plus Oral Solution (Ireland. Chanelle Pharmaceuticals Manufacturing Ltd.) Me-too Nayverm 1.5% W/V Oral Solution M/s. Saymans Pharmaceuticals (Pvt) Ltd. Lahore.	i) As per Form-5 the firm has changed brand name to Levozide Worm Drench 1.5% w/v (vet). ii) Moreover, the initial original registration letter (issued in 1985) does not contain detail composition. iii) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. iv) Latest inspection report of M/s. Intervac for Liquid Section.	**i)** Regarding change of brand name, it is a typographic mistake. We feel sorry for that and again submitting the Form-5. **ii)** Regarding initial original registration letter does not contain detail composition, it is not practiced by the MOH that time. **iii)** Form 5 dully signed by the contract giver/registration holder provided. **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	031478 06-10-2003 26-09-2008 03-10-2013	a. N.A 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. ii) Latest inspection report of M/s. Intervac for Liquid Section.	**i)** Form 5 dully signed by the contract giver/registration holder provided. **ii)** Latest inspection report of M/s. Intervac (Pvt) Ltd. For liquid section provided.

		letter) 100ml 250ml 500ml 1000ml 5000ml			iii) Master formula is not correct.	**iii)** Master formula of Fendanid Plus Liquid provided.
6.	-do-	Sulphadin Injection (Vet) Each 100ml contains:- Sulphadimidine Sodium…….. 33.33gm (Composition as per Form-5) 100ml	000789 01-07-1976 Last renewal application submission date 29-06-2016.		i) Initial registration letter not provided. 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. iii) Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.	**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". **ii)** Regarding the 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". **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, 9.5Km Sheikhupura 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, 9.5Km Sheikhupura 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).

Registration Board in its 288th meeting 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.

In response the firm submitted that the completion of the construction and installation of the machinery will be completed in the period of two years and six months. Furthermore, firm provided list of other registered products for toll manufacturing.

Sr. No.	***Regn. No.***	***Name of Drug(s)/ Composition***	***Dosage Form***	***Strength***	***Pack Size***
1.	010786	Adrenaline Each 100ml contains:- Adrenaline … 0.1gm (1 in 1000)	Injection	1mg/ml.	25ml
2.	031476	Atrosin Each ml contains:- Atropine Sulphate…… 1mg	Injection	1mg/ml	10ml 25ml
3.	008036	Calcifort Each 100ml contains:- Dextrose……...15.00 gm Calcium borogluconate……22.10 gm Magnesium Borogluconate... 6.00 gm Calcium hypophosphite ……1.37 gm Water for injection……...100ml	Injection		100ml
4.	003118	Gluco-P Each 100ml contains:- Calcium Borogluconate…16.60 gm Boric Acid ……. ….3.40gm	Injection		650ml
5.	028534	Rimoxyn 20% LA Each ml contains:- Oxytetracycline HCL……200mg	Injection	200mg	50ml 100ml
6.	028533	Rimoxyn PVP-100 Each ml contains:- Oxytetracycline HCl……...100mg	Injection	100mg	50ml 100ml

7.	032201	Gluco-P Plus Each 100ml contains:- Calcium Gluconate……..26.6gm Boric Acid …….5.4gm	Injection		300ml 450 ml
8.	057104	Septrocin Injection Each ml contains:- Trimethoprim ……..80mg Sulfadiazine……400mg	Injection		10ml 50ml 100ml
9.	058964	Amoxyn-LA Injection Each ml contains:- Amoxicillin (as trihydrate)….150mg	Injection	150mg/ml	50ml 100ml
10.	058965	Mepracin Injection 5% Each ml contains:- Mepyramine Maleate……..50mg	Injection	50mg/ml	10ml 50ml
11.	081322	Ketoplus Each ml contains:- Ketoprofen B.P. …….. 100mg	Injection	100mg/ml	50ml
12.	084970	D-Flam Injection Each ml contains:- Aceclofenac …… 25mg	Injection	25mg/ml	50 ml
13.	084971	Difnac Injection 10mg Each ml contains:- Meloxicam …… 10mg	Injection	10mg/ml	50ml
14.	084972	Phosphocare-P Injection Each ml contains:- Sodium Acid Phosphate…..400mg	Injection	400mg/ml	100ml
15.	084973	Tylo-PD Injection Each ml contains:- Tylosin Tartrate ……. 200mg	Injection	200mg/ml	100 ml
16.	028532	Evomec 0.08% Each 100ml contains :- Ivermectin……0.08gm.	Worm Drench	0.08% W/V	100ml 250ml 500ml 1000ml 5000ml
17.	031477	Fendanid Liquid Contains:- Oxfendazole……2.265 % W/V Oxyclozonide…… 6.25 % W/V	Liquid		100ml 250ml 500ml 1000ml 5000 ml
18.	028535	Fenzole 2.265% Each ml contains:- Oxfendazole……..22.65%	Worm Drench	2.265% W/V	100ml 1 Litre
19.	028536	Levozide 2.5% Each ml contains:- Levamisole HCl……25mg	Worm Drench	2.5% W/V	100ml 250ml 500ml 1000ml
20.	057103	Septrocin Oral Suspension Each ml contains:- Trimethoprim ……..80mg Sulfadiazine ……...400mg	Suspension		50ml 200ml 1 Litre

Decision:- **Registration Board deferred the case for obtaining details from the firm regarding timelines for completion of renovation of Oral and Injectable veterinary sections as the already provided information does not provide details about same.**

Case No. 56:- Show Cause Notices issued to the firms having registration of products containing Novaminsulfon.

Registration Board in its 277th meeting held on 27-29th December, 2017 meeting while rejecting applications of veterinary drugs containing Novaminsulfon due to earlier decisions of cancelling registration of metamizole containing human drugs for being associated with serious adverse effects like agranulocytosis. Accordingly show cause notices were issued to the firms having registrations of aforementioned drug formulations. A number of firms have responded with their point of view including request for personal hearings.

The salient points, of the responses received are summarized as under:-

i) Novaminsulfonis being used worldwide even in the countries which are being regulated by European Medicine Agency (EMA), MHRA and other countries like Canada. Novaminsulfon (Methampyrone, Dipyrone, Analgin, Metamizole) is allowed to use in veterinary drugs all over these countries. It is pertinent to note that the clinical study environments in US and in Pakistan are completely different and to take such strong action against the stakeholder who has invested millions in the products under consideration.

ii) The metamizole sodium is best drug of choice in emergency pain management of animals. Because this drug is registered in strict regulatory authorities like EMA, MHRA and Health Canada.

iii) Metamizole is a non-steroidal anti-inflammatory drug has been banned for human consumption not for veterinary drugs in the world. For veterinary Metamizole is not banned in any foreign and SRA countries. It is commonly used in the horse, cattle, pigs and dose as an antipyretic, analgesic and anti-inflammatory drug. The drug containing Metamizole is currently in use many foreign and SRA countries.

iv) A number of the firm requested for opportunity for personal hearing.

Decision:- Keeping in view the above stated position, Registration Board decided to call up all the above mentioned firms for personal hearing in the next meeting of Registration Board.

Case No. 57:- Request of M/s. Hilton Pharma (Pvt) Ltd., Karachi for Grant of Additional Packs for their already Registered Veterinary Drugs.

M/s. Hilton Pharma (Pvt) Ltd., Karachi has applied for grant of additional packs of their following registered veterinary drugs as per details mentioned against each:-

S.No.	Regn. No.	Name of Drug(s)/Composition	Already Pack Size Granted	Demanded Additional Pack	Initial registration with renewal	Justification
1.	084849	Mycohil Granules Each gm contains:- Tylosin Tartrate…...10% w/w Doxycycline HCL…20% w/w Bromhexine……0.5% w/w (As per Innovator's Specification*)	100gm 500gm 1Kg 5Kg Aluminum Sachet	2Kg 3Kg 4Kg 6Kg	18th August, 2017	*"To comply with market needs and cost effectiveness of the product"*

M/s. Hilton Pharma (Pvt) Ltd., Karachi has deposited the required fee of Rs.20,000/- and submitted following supporting documents:-

(i) Attested copy of initial registration letter.
(ii) Attested copy of CRF.
(iii) Attested copy of Drug Manufacturing License.
(iv) Undertaking that the provided information/documents are true/correct.
(v) GMP inspection conducted by DRAP conducted on 17-07-2018.
(vi) Attested copy of labels.

The demanded packs are not given to other firms.

Decision:- **Registration Board approved the grant of following additional pack sizes to registered product of M/s. Hilton Pharma (Pvt) Ltd., Karachi on same terms and conditions;**

S.No.	Regn. No.	Name of Drug(s)/Composition	Approved Additional Pack
1.	**084849**	**Mycohil Granules** **Each gm contains:-** **Tylosin Tartrate…...10% w/w** **Doxycycline HCL…20% w/w** **Bromhexine……0.5% w/w**	**2Kg** **3Kg** **4Kg** **6Kg**

Case.No.58: REQUEST OF M/S. FRESENIUS MEDICAL CARE PAKISTAN (PVT) LTD, LAHORE FOR CHANGE OF MANUFACTURING SITE FOR REGISTERED PRODUCTS.

The case was presented in 281st meeting of Registration Board for change of manufacturing site / source of their following already registered products as under: -

S. No	Reg. No.	Name of Drugs / Composition / Reg. No.	Existing approved site (manufacturer)	New Proposed Site / Product License Holder (as per COPP)
1.	039884	CAPD/DPCA 2 Stay safe Peritoneal Dialysis Solution. **As per initial reg.letter** Each Liter contains: - Sodium Chloride 5.786gm. Sodium Lactate 3.925gm. Calcium Chloride 0.2573gm. Magnesium Chloride 0.1017gm. Glucose Monohydrate 16.5gm (Anhydrous glucose 15gm.) **As per Form-5A & COPP.** Each Liter contains: - Sodium Chloride 5.786gm. Sodium Lactate 3.925gm. Calcium Chloride **Dihydrate** 0.2573gm Magnesium Chloride **Hexahydrate** 0.1017gm Glucose Monohydrate 16.5gm.	M/s Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany.	**Name & Address of Manufacturer:** M/s. Fresenius Medical Care Production SDN, BHD. Lot 34618, PT 29466, Techpark @ Enstek, Bandar Enstek Nilai, 71760 Negeri Sembilan, Malaysia. **Product License Holder:** M/s Fresenius Medical Care Malaysia Sdn. Bhd. Second Floor Axis Technology Centre, Lot 13 Jalan 51 A/225, 46100 Petaling Jaya, Malaysia.
2.	039886	CAPD/DPCA 3 Stay safe Peritoneal Dialysis Solution. **As per initial reg.letter.** Each Liter contains: - Sodium Chloride 5.786gm. Sodium Lactate 3.925gm. Calcium Chloride 0.2573gm. Magnesium Chloride 0.1017gm. Glucose Monohydrate 46.75gm (Anhydrous glucose 42.5gm) **As per Form-5A & COPP.** Each Liter contains: - Sodium Chloride 5.786gm Sodium Lactate 3.925gm Calcium Chloride **Dihydrate** 0.2573gm Magnesium Chloride **Hexahydrate** 0.1017gm Glucose Monohydrate 46.75gm	**-do-**	**-do-**
3.	039887	CAPD/DPCA 4 Stay safe Peritoneal Dialysis Solution. **As per initial reg.letter.** Each Liter contains: - Sodium Chloride 5.786gm. Sodium Lactate 3.925gm. Calcium Chloride 0.2573gm. Magnesium Chloride 0.1017gm. Glucose Monohydrate 46.75gm (Anhydrous glucose 22.73gm)	**-do-**	**-do-**

		As per Form-5A & COPP. Each Liter contains: - Sodium Chloride 5.786gm Sodium Lactate 3.925gm Calcium Chloride **Dihydrate** 0.2573gm Magnesium Chloride **Hexahydrate** 0.1017gm **Glucose Monohydrate 25.0gm**		

The firm has deposited fee of Rs.50,000/- (for each product) with following supporting documents.

a) Application on Form-5A .
b) Original CoPP issued by Malaysia Drug Control Authority for new manufacturing site.
c) Authorization letter in original.
d) Copy of GMP Certificate for new manufacturing site issued by Ministry of Health Malaysia.
e) Copy of initial registration letter and post registration variations.
f) Site master file of new manufacturing site.

The last renewal of the products has been submitted after due date but with 60 days of time with double fee.

Decision of 281st Meeting:-
Registration Board deferred the case for confirmation of renewal status from RRR section as the firm has submitted for last renewal of the said products after due date but within sixty days of expiry of validity with double fee.

The case was further presented in 286th meeting by RRR section with reference to the Decision of 281st meeting and decided as under: -

Decision of 286th Meeting: -
Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 09-09-2015 to 08-09-2020 subject to prevailing import policy for the manufacturer abroad.

Decision:- Registration Board approved the following changes in respect of registered products CAPD/DPCA 2 Stay safe Peritoneal Dialysis Solution (Reg.No. 039884), CAPD/DPCA 3 Stay safe Peritoneal Dialysis Solution (Reg.No. 039886), CAPD/DPCA 4 Stay safe Peritoneal Dialysis Solution (Reg.No. 039887) subject to policy for imported finished drug registration. Other terms and conditions remain the same.

S. No	Reg. No.	Name of Drugs / Composition / Reg. No.	Existing approved site (manufacturer)	New Proposed Site / Product License Holder (as per COPP)
1.	039884	CAPD/DPCA 2 Stay safe Peritoneal Dialysis Solution. **As per Form-5A & COPP.** Each Liter contains: - Sodium Chloride 5.786gm. Sodium Lactate 3.925gm. Calcium Chloride **Dihydrate** 0.2573gm Magnesium Chloride **Hexahydrate** 0.1017gm Glucose Monohydrate 16.5gm.	M/s Fresenius Medical Care Deutschland GmbH, St. Wendel, Germany.	**Name & Address of Manufacturer:** M/s. Fresenius Medical Care Production SDN, BHD. Lot 34618, PT 29466, Techpark @ Enstek, Bandar Enstek Nilai, 71760 Negeri Sembilan, Malaysia. **Product License Holder:**M/s Fresenius Medical Care Malaysia Sdn. Bhd. Second Floor Axis Technology Centre, Lot 13 Jalan 51 A/225, 46100 Petaling Jaya, Malaysia.

2.	039886	CAPD/DPCA 3 Stay safe Peritoneal Dialysis Solution. **As per Form-5A & COPP.** Each Liter contains: - Sodium Chloride 5.786gm Sodium Lactate 3.925gm Calcium Chloride **Dihydrate** 0.2573gm Magnesium Chloride **Hexahydrate** 0.1017gm Glucose Monohydrate 46.75gm	**-do-**	**-do-**
3.	039887	CAPD/DPCA 4 Stay safe Peritoneal Dialysis Solution. **As per Form-5A & COPP.** Each Liter contains: - Sodium Chloride 5.786gm Sodium Lactate 3.925gm Calcium Chloride **Dihydrate** 0.2573gm Magnesium Chloride **Hexahydrate** 0.1017gm **Glucose Monohydrate 25.0gm**	**-do-**	**-do-**

Case.No.59: REQUEST OF M/S ATCO PHARMA INTERNATIONAL PRIVATE LIMITED, KARACHI. FOR CHANGE IN MANUFACTURING SITE.

M/s Atco Pharma International Private Limited, B-18, SITE, Karachi has stated that their principal manufacturer M/s Fresenius Kabi Oncology Limited, India wants to transfer its products from existing manufacturing facility to its MHRA approved manufacturing facility while the name of manufacturer remain the same of their following registered products as per details given below: -

S. No	Name / Composition / Reg. No.	Existing Manufacturing Site (as per approval)	Proposed Site / Manufacturer & Marketing Authorization Holder
1.	Fytosid 100mg Injection Each ml contains:- Etoposide USP ……20mg	Manufacturer: M/s Fresenius Kabi Oncology Limited, 19, HPSIDC, Industrial Area, Baddi, Distt. Solan, India	Name & Address of New Manufacturer: M/s Fresenius Kabi Oncology Limited, Village-Kishanpura, P.O. Guru Majra, Tehsil-Nalagarh, Distt. Solan (H.P.)-174101, India. Marketing Authorization Holder: As above
2.	Adrim 50mg/25ml Injection Each ml contains:- Doxorubicin HCL…..2mg	-do-	-do-
3.	Adrim 10mg/5ml Injection Each ml contains:- Doxorubicin HCL…. 2mg	-do-	-do-
4.	Zexate 50mg/2ml Injection Each ml contains:- Methotrexate Sodium Eq to Methotrexate USP 25mg	-do-	-do-
5.	Zexate 500mg/20ml Injection Each ml contains:- Methotrexate Sodium Eq to Methotrexate USP 25mg	-do-	-do-
6.	Irinotel 100mg/5ml injection	-do-	-do-

	Each ml contains: - Irinotecan Hydrochloride Trihydrate 20.00mg		
7.	Irinotel 40mg/2ml injection Each ml contains: - Irinotecan Hydrochloride Trihydrate 20.00mg	-do-	-do-
8.	Kemocarb 150mg/15ml Injection Each ml contains: - Carboplatin BP 10.0mg	-do-	-do-
9.	Kemocarb 450mg/45ml Injection Each ml contains: - Carboplatin BP 10.0mg	-do-	-do-

The firm has submitted the following supporting documents:

a. Total fee of Rs.900,000/- (9x100,000/-) .
b. Original and legalized COPP's.
c. Attested copy of GMP certificate issued by MHRA based on the inspection conducted on 08-02-2016.
d. Initial Registration letters with renewal status
e. Copy of valid Drug License by way of whole sale.
f. Copy of site master file of new manufacturing site.
g. Copy of letter for change of manufacturer name from M/s Dabur Pharma Ltd, India to M/s Fresenius Kabi Oncology Ltd, India.

The initial registration letters issued on 15-02-2007 for the products mentioned at Sr. No.1 2 & 3 and due date was 14-02-2012, the firm has submitted renewal applications on 15-02-2012 which is one day late.

Decision:- Registration Board deferred the products for the confirmation of renewal status.

Case.No.60: REQUEST OF M/S ATCO LABORATORIES LIMITED KARACHI FOR CHANGE OF MANUFACTURING SITE.

M/s Atco Laboratories Limited, B-18, SITE, Karachi has stated that their principal manufacturer M/s Fresenius Kabi Oncology Limited, India wants to transfer its products from existing manufacturing facility to its MHRA approved manufacturing facility while the name of manufacturer remain the same of their following registered products as per details given below: -

S. No	Name / Composition / Reg. No.	Existing Manufacturing Site (as per approval)	Proposed Site / Manufacturer & Marketing Authorization Holder
1.	Intaxel 30mg/5ml Injection. Each ml contains:- Paclitaxel USP …..6mg Reg. No.044881.	**Manufacturer:** M/s Fresenius Kabi Oncology Limited, India	**Name of New Manufacturer & Marketing Authorization Holder:** M/s Fresenius Kabi Oncology Limited, Village Kishanpura, P.O. Guru Majra, Tehsil. Nalagarh, Distt. Solan (H.P.)-174 101, India.
2.	Intaxel 100mg/16.7ml Injection.	-do-	-do-

	Each ml contains:- Paclitaxel USP …..6mg Reg. No.044882		
3.	Intaxel 150mg/25ml Injection. Each ml contains:- Paclitaxel USP …..6mg Reg. No.045707	-do-	-do-
4.	Intaxel 260mg/43.4ml Injection. Each ml contains:- Paclitaxel USP …..6mg Reg. No.045708	-do-	-do-
5.	Intaxel 300mg/50ml Injection. Each ml contains:- Paclitaxel USP …..6mg Reg. No.045709	-do-	-do-
6.	Cytarine 1gm/10ml Injection Each ml contains:- Cytarabine B.P. 100mg Reg. No.045710	-do-	-do-
7.	Cytarine 100mg/1ml Injection Each ml contains:- Cytarabine B.P. 100mg. Reg. No.044871	-do-	-do-
8.	Cytarine 500mg/5ml Injection Each ml contains:- Cytarabine B.P. 100mg. Reg. No.044872	-do-	-do-

The firm has submitted the following supporting documents: -

a. Total fee of Rs.800,000/- (8x100,000/-) .
b. Original and legalized COPP's.
c. Attested copy of GMP certificate issued by MHRA based on the inspection conducted on 08-02-2016.
d. Initial Registration letters with renewal status
e. Copy of valid Drug License by way of whole sale.
f. Copy of site master file of new manufacturing site.
g. Copy of letter for change of manufacturer name from M/s Dabur Pharma Ltd, India to M/s Fresenius Kabi Oncology Ltd, India.

The initial registration letters issued on 15-02-2007 for the products mentioned at Sr. No.1, 2, 7 & 8 and due date was 14-02-2012, the firm has submitted renewal applications on 15-02-2012 which is one day late.

Decision: **Registration Board approved the above changes in respect of registered products Intaxel 150mg/25ml Injection (Reg.No. 045707), Intaxel 260mg/43.4ml Injection. (Reg.No. 045708), Intaxel 300mg/50ml Injection. (Reg.No. 045709) Cytarine 1gm/10ml Injection (Reg.No. 045710), Cytarine 100mg/1ml Injection (Reg.No. 044871) subject to policy for imported finished drug registration. Other terms and conditions remain the same. The board deffered the products at Sr no. 1,2,7 and 8 for confirmation of renewal status.**

Case.No.61: Recording of Composition of Products with Equivalency Factor as per CoPP of M/S. Servier (Pvt) Ltd, Lahore.

Registration Board approved the correction in composition of following products of M/s. Servier (Pvt) Ltd, Lahore in 274th meeting.

S. No	Product name and composition (as per 268th meeting minutes)	Product name and composition (correct composition)
1.	Triplixam 5/1.25/5 Film coated Tablet Each film coated tablet contains: Perindopril Arginine.....5mg Indapamide… 1.25mg **Amlodipine…10mg**	Triplixam 5/1.25/5 Film coated Tablet Each film coated tablet contains: Perindopril Arginine…5mg Indapamide…1.25mg **Amlodipine…5mg**
2.	Triplixam10/2.5/10 film coated Tablet Each film coated tablet contains; Perindopril Arginine….5mg **Indapamide…1.25mg** Amlodipine…10mg	Triplixam 10/2.5/10 Film coated Tablet Each film coated tablet contains; Perindopril Arginine….10mg **Indapamide….2.5mg** Amlodipine…. 10mg
3.	Triplixam10/2.5/5 Film coated Tablet Each film coated tablet contains; Perindopril Arginine….5mg Indapamide…1.25mg **Amlodipine…10mg**	Triplixam 10/2.5/5 Film coated Tablet Each film coated tablet contains; Perindopril Arginine…. 10mg Indapamide…. 2.5mg **Amlodipine…. 5mg**

The complete composition of above products (with Equivalency factor) as per COPP included in registration letters as per following details.

S. No	Product name and composition (correct composition) M-274	Recording of Composition of Products With Equivalency Factor as per COPP
1.	Triplixam 5/1.25/5 Film coated Tablet Each film coated tablet contains: Perindopril Arginine…5mg Indapamide…1.25mg **Amlodipine…5mg**	Triplixam 5/1.25/5 Film coated Tablet Each film coated tablet contains: Perindopril ……. 3.395mg equivalent to 5mg perindopril arginine Indapamide… 1.25mg Amlodipine besilate…… 6.935mg equivalent to 5mg amlodipine.
2.	Triplixam 10/2.5/10 Film coated Tablet Each film coated tablet contains; Perindopril Arginine….10mg **Indapamide….2.5mg** Amlodipine…. 10mg	Triplixam 10/2.5/10 Film coated Tablet Each film coated tablet contains; Perindopril ……. 6.790mg equivalent to 10mg perindopril arginine Indapamide… 2.50mg Amlodipine besilate…… 13.870mg equivalent to 10mg amlodipine.
3.	Triplixam 10/2.5/5 Film coated Tablet Each film coated tablet contains; Perindopril Arginine…. 10mg Indapamide…. 2.5mg **Amlodipine…. 5mg**	Triplixam 10/2.5/5 Film coated Tablet Each film coated tablet contains; Perindopril ……. 6.790mg equivalent to 10mg perindopril arginine Indapamide… 2.50mg Amlodipine besilate…… 6.935mg equivalent to 5mg amlodipine.

The address of the firm is mentioned as "M/s. Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd, 65 Main Boulevard Gulberg, Lahore" in minutes. However, the address as per DSL is "M/s. Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd, 9-KM, Lahore Sheikhupura Road Near Dosaco Chowk, Kot Abdul Malik, Tehsil Ferozewala District Sheikhupura" incorporated in registration letter for the following products: -

S.No	Name of Product	Name of Firm
1.	Triplixam 5/1.25/5 Film coated Tablet	M/s. Servier Research and Pharmaceuticals Pakistan (Pvt) Ltd, Lahore
2.	Triplixam 10/2.5/10 Film coated Tablet	-do-
3.	Triplixam 10/2.5/5 Film coated Tablet	-do-

4.	Triplixam 5/1.25/10 Tablet	-do-
5.	Lonsurf 15mg Film Coated Tablet	-do-
6.	Lonsurf 20mg Film Coated Tablet	-do-
7.	Pixuvri powder for concentrate for solution for infusion	-do-

Decision: Registration Board noted the information.

Case.No.62: REQUEST FOR CHANGE OF MANUFACTURING SITE OF M/S OBS PAKISTAN PRIVATE LIMITED, KARACHI.

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.	Name & Composition (as per approval & COPP).	Existing approved site (as per approval letters)	New Proposed Site / Manufacturer / MAH as per COPP
1.	021100	**As per approval.** Trusopt Ophthalmic Solution. Each ml of Trusopt 2% contains: - 20mg dorzelamide hydrochloride (22.3mg of dorzolamide hydrochloride). **as per COPP.** Trusopt (Dorzolamide Hydrochloride). Each 1ml contains: - Dorzolamide…….20mg eq to Dorzolamide Hydrochloride 22.26mg	**Manufacturer as per Initial R.letter:** M/s Merck Sharp & Dhome B.V., Holland (MSD) **Change of Manf. & MAH in M-276** <u>Manufacturer:</u> M/s. Laboratoires Merck Sharp & Dohme- Chibret, Route de Marsat, Riom, 63963 Clermont Ferrand Cedex 9, France. <u>Marketing Authorization Holder:</u> M/s. MSD France, 34, avenue Leonard de Vinci, 92400 Courbevoie, France.	**Name & Address of Manufacturer:** M/s Santen Pharmaceutical Co. Ltd. Noto Plant, 2-14, Shikinami, Hodatsushimizu-cho, Hakui-gun, Ishikawa, Japan. **Marketing Authorizatio Holder & Batch Release** 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 & legalized COPP issued Finnish Medicines Agency.
e) Letter of authorization
f) NOC from proposed & current manufacturer.
g) GMP certificate of new site.

Decision: Registration Board approved the above changes in respect of registered products Trusopt Ophthalmic Solution (Reg.No. 021100) subject to policy for imported finished drug registration. Other terms and conditions remain the same.

Case.No.63:- REQUEST OF M/S. FRESENIUS KABI PAKISTAN, LAHORE FOR REGISTRATION OF DRUGS.

M/s. Fresenius Kabi Pakistan, 1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27-C/3, Gulberg-III, Lahore has applied for registration of following products in their own name

and cancellation from the name of previous importer i.e M/s Medipak Limited, Kot Lakhpat, Lahore. Details of each proposed product is as under:

Product: Fresofol 1% Emulsion for intravenous injection (Reg.No.027384)		
S. No.	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**Fresofol 1% Emulsion for intravenous injection** Each ml emulsion contains: - Propofol……10mg
2.	Name and address of Applicant (transferee) office address	M/s. Fresenius Kabi Pakistan, 1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27-C/3, Gulberg-III, Lahore.
3.	Name of Transferor	M/s. Medipak Limited, Kot Lakhpat, Lahore.
4.	Detail of Drug Sale License	M/s. Agility Logistics (Pvt) Ltd, Godown address: RLC-2, 26-KM, Multan Road, Opposite Hussaini Darbar, Near Shamshad Farm House, Lahore.
5.	Name and address of manufacturer.	**Manufacturer: -** M/s. Fresenius Kabi Austria GMBH Hafnerstrasse 36 Graz – A-8055, Austria. & M/s. Fresenius Kabi AB Rapsgastan, 7 Uppsala - S-75174 Suecia/Sweden.
6.	Name and address of Product Licesne Holder	M/s. Fresenius Kabi Deutschland GMBH Else-Kroner Strasse, 1 Bad Homburg - D-61352 Alemania / Germany
7.	Name of exporting country	Spain
8.	Diary No. & Date of R& I	Dy. No. 2235 Dated 17-01-2019
9.	Finished Product Specification	Ph Eur
10.	Shelf life	36 months
11.	Pack Size	5x20ml/pack (glass ampoules)

The firm has deposited fee of Rs. 100,000/- and provided the following supporting documents;

a) Copies of initial registration letters and renewal status.
b) Termination letter (original) from manufacturer / product license holder in favor of current registration holder i.e. M/s Medipak Limited, Kot Lakhpat, Lahore.
c) NOC (original) from existing registration holder for transfer of registrations (23-01-2018).
d) Original & legalized COPP issued by Spanish Authority's.
e) Letter of Authorization (original & legalized for the product Fresofol Injection 1%. issued by manufacturer / product license holder for new proposed sole agent.
f) Order sheet passed by Civil Judge 1st Class, Lahore in original.

With reference to the instant case it is informed that M/s. Medipak Limited, Lahore through M/s. Hassan filed a suit (dated: 06-09-2016) in the Court of Senior Civil Judge Lahore against M/s. Fresenius Kabi regarding termination of Distribution and License Agreement (including products Ketosteril Tablet, Fresofol 1% Emulsion for IV injection and Nephrosteril IV infusion) with M/s Medipak Limited, Lahore in which Secretary Registration Board & DRAP were also made party. The case was pursued by PE&R Division for submission of parawise comments and statements, as and when directed by the Honorable court, on behalf of Secretary Registration Board & DRAP through Legal Affairs Division.

Subsequently, M/s. Fresenius Kabi filed a Revision application (CR.No.29480/2017) in the Lahore High Court, Lahore wherein Secretary Registration Board and Drug Regulatory Authority of Pakistan were made respondents.

Now M/s. Fresenius Kabi Pakistan (Pvt) Ltd, Lahore has provided attested copy of court settlement Order dated; 11-01-2018 between M/s. Medipak Limited, Lahore and M/s. Fresenius Kabi Deutschland Gmbh & M/s. Fresenius Kabi representative office, UAE.

Decision:- Keeping in view the above position, Registration Board decided as follows;

a. **Cancellation of registration of Fresofol 1% Emulsion for intravenous injection (Reg.No. 027384) from the name of M/s. Medipak Limited, Kot Lakhpat, Lahore.**
b. **Registration of Fresofol 1% Emulsion for intravenous injection (Reg.No. 027384) in the name of M/s. Fresenius Kabi Pakistan, 1st Floor, Tanwir Ahmed Medical Center, MM Alam Road, 27-C/3, Gulberg-III, Lahore as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).**
c. **Reference shall be sent to Costing & Pricing Division for their Comments regarding MRP of the said product.**

Case.No.64: REQUEST OF M/S ROCHE PAKISTAN LIMITED, KARACHI FOR CHANGE IN ADDRESS.

M/s Roche Pakistan Limited, Karachi has informed that their head office address has changed as per following details:-

Head Office Address

As per old DSL	As per new DSL
M/s Roche Pakistan Limited, 37-C, Block – 6 P.E.C.H.S, Karachi	M/s Roche Pakistan Limited, 1st Floor, 37-B, Block – 6 P.E.C.H.S,Karachi

Ware House Address

As per old DSL	As per new DSL
39-C/1 Block-6, P.E.C.H.S, Karachi	R-PI, Plot No. 116, Sector 15, K.I.A, Karachi and R-PI, Plot No. 56, Sector 15, K.I.A, Karachi

Name of Proprietor

As per old DSL	As per new DSL
Mr. Shahid Akhtar Shaikh	Mr. Shoukat Ali

The firm has requested to update the current address to their already registered following products: -

S. No	Name of Product / Composition	Reg. No.	Renewal Status
1.	Bonviva 3mg/3ml PFS	047663	Firm has submitted complete renewal trail.
2.	Cellcept 500mg FC Tablet	028451	
3.	Tarceva 100mg Tablet	043002	
4.	Tarceva 150mg Tablet	043003	
5.	Valcyte 450mg Tablet	052253	
6.	Bonviva 150mg Tablet	044820	RRR section has confirmed the renewal status.
7.	Tamiflu 75mg Capsule	039619	
8.	Xeloda 500mg Tablet	027375	

The firm has submitted following supporting documents / information for approval:-

a) Fee of Rs.5000/- for each product.
b) Copy of previous & new DSL.
c) Initial registration letters and renewal trail.

Decision: **Keeping in view the valid Drug Sale License, Registration Board approved the change in address of importer of above products as per following changes, subject to storage facility verification of new address**.

Head Office Address (As per New DSL)	Ware House Address (As per new DSL)
M/s Roche Pakistan Limited, 1st Floor, 37-B, Block – 6 P.E.C.H.S,Karachi	R-PI, Plot No. 116, Sector 15, K.I.A, Karachi and R-PI, Plot No. 56, Sector 15, K.I.A, Karachi

Case.No.65: SHORTAGE OF FORANE (ISOFLURANE) LIQUID FOR INHALATION 100ML

M/s Getz Pharma has intimated DRAP for discontinuation of their marketed product "Forane Liquid for Inhalation 100ml (Isoflurane 99.9% w/w) (Reg. No.011081) as M/s AbbVie, Malaysia has informed them that this shortage is due to an unexpected suspension of manufacture of API by AbbVie's third party manufacturing facility. M/s Getz Pharma submitted that on the basis of this reason we will no longer be able to continue the marketing of above-mentioned product. Submitted for consideration of Registration Board.

Decision: Registration Board deferred the case for further deliberation.

Case.No.66: REQUEST OF M/S GALAXY PHARMA (PVT) LTD, KARACHI FOR CHANGE OF MANUFACTURING SITE.

M/s Galaxy Pharma (Pvt) Ltd, D-180, Rojhan Street, Block-5, Karachi has applied for change of manufacturing site of their following already registered products as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter).	Existing approved site (as per approval letter)	New Proposed Site / Manufacturer / PLH
1.	062214	Utrogestan 100mg Capsule. Each Capsule contains: - Micronized Progesterone….100mg	M/s Besins Healthcare, Brussels, Belgium.	**Name & Address of Manufacturer:-** M/s Cyndea Pharma, S.L., Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110 (Soria) Spain **Product License Holder: -** M/s Besins Healthcare Benelux 287, Avenue Louise 1050 Bruxelles (Belgium)
2.	059079	Utrogestan Vaginal 200mg soft Capsule. Each Capsule contains: - Micronized Progesterone….200mg	-do-	-do-

The firm has submitted the following supporting documents: -

a) Fee of Rs.200,000/- for both products.
b) Application on Form 5A
c) Copy of initial registration letter
d) Renewal trail of both products
e) Original & legalized COPP issued Belgium Authority's.
f) Original & Legalized GMP certificate issued by Spanish Authority's of new site.
g) Site master file for new manufacturing site.

The case was presented in 288th meeting of Registration Board by RRR section for regularization of renewal period and Board decided as under: -

Sr. No	Products Name & Reg. No	Application receiving date and fee submitted date and due date	Decision
1	Utrogestan Vaginal 200mg Soft Capsule Reg. No. 059079	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
2.	Utrogestan Vaginal 100mg Soft Capsule Reg. No. 062214	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

288th Meeting Decision: Registration Board acceded to the request of the firm and decided in last column mentioned above.

Decision: Registration Board approved the following changes in respect of registered products Utrogestan 100mg Capsule (Reg.No. 062214) and Utrogestan Vaginal 200mg soft Capsule (Reg.No. 059079) subject to policy for imported finished drug registration. Other terms and conditions remain the same.

S. No	Reg. No.	Name & Composition (as per initial letter).	Existing approved site (as per approval letter)	New Proposed Site / Manufacturer / PLH
1.	062214	Utrogestan 100mg Capsule. Each Capsule contains: - Micronized Progesterone….100mg	M/s Besins Healthcare, Brussels, Belgium.	**Name & Address of Manufacturer:-** M/s Cyndea Pharma, S.L., Poligono Industrial Emiliano Revilla Sanz, Avenida de Agreda, 31, Olvega 42110 (Soria) Spain **Product License Holder: -** M/s Besins Healthcare Benelux 287, Avenue Louise 1050 Bruxelles (Belgium)
2.	059079	Utrogestan Vaginal 200mg soft Capsule. Each Capsule contains: - Micronized Progesterone….200mg	-do-	-do-

Case.No.67: REQUEST OF M/S MARTIN DOW LIMITED, KARACHI FOR REGISTRATION OF DRUGS.

M/s Martin Dow Limited, Plot No. 37, Sector, 19, Korangi Industrial Area, Karachi has applied for registration of following product in their own name and cancellation from the name of previous importer i.e M/s Roche Pakistan Limited, 37-C,Block 6, P.E.C.H.S., Karachi. Details of proposed product is as under:-

Product: Kytril Ampoule 3mg / 3ml (Granisetron Hydrochloride)		
S. No.	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Kytril Ampoule 3mg / 3ml **As per record :-** Each ampoule contains: 3mg granisetron (freebase) as the hydrochloride salt in 0.9% saline.

		As per COPP (issued by French authority) Each 3ml solution contains:- Granisetron hydrochloride……3.36mg. Quantity Corresponds to base granisetron……..3.0mg
2.	Name and address of Applicant (transferee)	M/s Martin Dow Limited, Plot No. 37, Sector, 19, Korangi Industrial Area, Karachi.
3.	Name of Transferor	M/s Roche Pakistan Limited, 37-C,Block 6, P.E.C.H.S., Karachi
4.	Detail of Drug Sale License	Address: M/s Martin Dow Limited, Plot No. 37, Sector, 19, Korangi Industrial Area, Karachi.
5.	Name and address of manufacturer	**As per Form-5A & approval:-** M/s Cenexi SAS, 52, rue M. et J. Gaucher 94120 Fontenay-sous-Bois, France. **As per COPP:-** M/s Roche Pharma AG, Emil-Barell Strasse I, 79639 Grenzach-Wyhlen, Baden-Wuerttemberg, Allemagne.
6.	Name and address of marketing authorization holder	M/s Atnahs Pharma UK Ltd, Sovereign House, Miles Gray Road Basildon, Essex, SS14 3FR, United Kingdom.
7.	Name of exporting country	France
8.	Diary No. & Date of R& I	Dy. No. 15457 Dated 25/04/2018
9.	Finished Product Specification	Not provided
10.	Shelf life	36 months (as per Form-5A)
11.	Pack Size	1's
12.	**Remarks:** • Difference in composition in between initial letter & COPP • Difference in name & address of manufacturer in between approval & COPP • Finished product specification not provided.	

The firm has submitted the following supporting documents / information for approval of above transfer of registration: -

a) Fee of Rs.100,000/-
b) Applications on Form-5A.
c) Copy of Drug Sale License.
d) Registration letters with renewal status.
e) Copy of Termination of current importer and authority letter for new proposed mporter from manufacturer.
f) NOC for transfer of registrations for both products.
g) Original legalized CoPP for Kytril Ampoule 3mg/3ml issued by French Authority's.

With reference to remarks column above, a letter issued to the firm for clarification / provision of documents and firm has submitted their reply as udner: -

S. No	Shortcomins / clarification	Reply by the firm
	Difference in composition in between initial letter & COPP.	The actual composition / lable claim as mentioned in the CoPP issued by the authority in France is mentioned below: Kytril 3mg/3ml injectable solution: Granisetron Hydrochloride……3.36mg Quantity corresponds to base granisetron…3.00mg The composition mentioned in the registration letter issued by DRAP is metoend below: Each ampoule contains: 3mg granisetron (free base) as the hydrochloride salt in 0.9% Both compositions indicate that granisetron hydrochloride (salt form) 3.36mg is used in the formulation which

		corresponds to organisetron (free base) 3.0mg, in the form of a concentrate in 0.9% saline. This concentrate will be further diluted as per the dosage and administration requirements for patients.
	As per your request manufacturer remains the same however, from the details mentioned in CoPP & approval, the manufacturer seems different.	Enclosed is the revised orginal and legalized CoPP as per requirmement. According to it, details are mentioned below for your easy reference. **Clause 2A.2 marketing authorization holder is:** Atnahs Pharma UK Ltd Sovereign House, Miles Gray Road Basildon, Essex, SS14 3FR United Kingdom. **Clause 2A.3.1 address of manufacturer and in-charge of the batch release is:** Cenexi 52 rue Marcel at Jacques SGaucher 94120 Fontenay-sous-Bois France. **Clause 2A.6 applicant is:** Cenexi 52 rue Marcel at Jacques SGaucher 94120 Fontenay-sous-Bois, France
	Finished product specification not provided.	Finish product specification has been provided.

Decision:- Keeping in view the above position, Registration Board decided as follows;

a. **Approved the cancellation of registration of Kytril Ampoule 3mg/3ml (Reg.No. 027384) from the name of M/s Roche Pakistan Limited, Karachi.**
b. **Approved the registration of Kytril Ampoule 3mg/3ml in the name of M/s. Martin Dow Limited, Korangi Industrial Area, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).**
c. **A reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the said product.**

Case.No.68: REQUEST OF M/S BAYER PAKISTAN (PVT) LTD, KARACHI FOR DE-REGISTRATION/ CANCELLATION OF REGISTRATION REGISTERED PRODUCT.

M/s Bayer Pakistan (Pvt) Ltd, Karachi has applied for de-registration/cancellation of registrations of following registered imported products as per details mentioned alongside.

DE-REGISTRATION OF DRUGS ON FIRM'S REQUEST					
S. No	**Firm Name**	**Product(s) Name**	**Reg. No**	**Reason for De-Reg (stated by firm)**	**Alternative registered product**
1.	M/S Bayer Pakistan (Pvt) Ltd, Karachi	Dopergin Tablet Each Tablet Contains: - Lisuride Hydrogen Maleate……0.2mg	009882	TEVA CZECH Republic was the single qualified source of Lisuride Hydrogen maleate worldwide & our parent company Bayer AG Germany procure this API from the same manufacturer. M/s Medipharm (Pvt) Ltd (now merged with M/s Bayer Pakistan) was getting same API from our	Other product containing Lisuride Hydrogen Maleate as an active ingredient is not available in Pakistan.

				principal Bayer AG Germany. Bayer AG has stopped the production / marketing of this product in Europe since 2013. To continue with this product in Pakistan we directly approached TEVA & based on our very less requirement of this API (i.e. less than 1kg) TEVA has shown his inability to produce API batches solely for Pakistan due to big production batch sizes.	
2.	-do-	Qlaira Tablet, Each wallet (28 film coated tablets) contains: - Part I (2 dark yellow film coated tablets-Core) Estradiol valerate….3.000 mg. Part II (5 medium red film-coated tablets-Core) Estradiol valerate….2.000 mg Dienogest…….2.000 mg Part III (17 light yellow film-coated tablets-Core) Estradiol valerate….2.000 mg Dienogest…….3.000 mg Part IV (2 dark red film-coated tablets-Core) Estradiol valerate….1.000 mg Part V (2 white film-coated tablets-Core) None	088370	• The business of this product is not viable. • Due to delayed registration, globally our principal has taken decision to not market this product. • Therefore, we are applying for cancellation / De-registration of this product to avoid unnecessary workload of life cycle management at both ends DRAP & Company.	Qlaira contains tow APIs: • Estradiol Valerate. • Dinogest (not available in pakistan). Company provided brands containing Estradiol Valerate as. Estranor, M/s Saffron Pharma. Norestra, M/s British Pharma ltd, Orgyluton, M/s Hansel Pharma, Progyluton, M/s Bayer Heatl care. Ovlogyn M/s Zafa.

The firm has also provided the following supporting documents:-

a. Copy of registration letter with last renewal status..
b. Justification (for de-registration/cancellation of registration).
c. An undertaking that no case is pending at any forum/court of law.

Decision: Registration Board deferred the case for confirmation of alternative registered products.

Case No.69: REQUEST OF M/S GLAXOSMITHKLINE PAKISTAN LIMITED, KARACHI FOR PERMISSION TO IMPORT REQUIP PD TABLETS IN GENERAL EXPORT (GE) PACK.

M/S Glaxosmithkline Pakistan Limited, Karachi has requested for for permission to import the following products in General Export packs: -

S. No.	Product(s) Description	Reg.No.	Registered Source
1.	Requip PD Tablet 2mg Each prolonged release tablets contains:- Ropinirole hydrochloride…2.280mg eq. to 2mg Ropinirole free base.	094747	Spain

2.	Requip PD Tablet 4mg Each prolonged release tablets contains:- Ropinirole hydrochloride…4.560mg eq. to 4mg Ropinirole free base	094748	Spain
3.	Requip PD Tablet 8mg Each prolonged release tablets contains:- Ropinirole hydrochloride…9.120mg eq. to 8mg Ropinirole free base	094749	Spain

The firm has mentioned following reasons to ensure sustained supply of the product: -

a. Manufacturing site has supply constraints and packaging of the product in country specific packs consumes more time and resources as compared to the packaging in General Export Packs which are being supplied to mos of the markets.
b. Constraints in technical and commercial feasibility of the manufacturing site due to requirement of specialized packaging only for Pakistan.
c. We may often face stocks availability issues if do not import in readily available General Export Pack.

The firm has stated that product registration number, MRP and urdu text will be printed locally through laser jet printer at their licensed premises (i.e.F-268, SITE, Karachi DML No.000233 by way of formulation) prior to market the products for an initial period of 03 years.

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.15000/-
b. Copy of registration letter (issued on 1st February, 2019).

Decision: **Registration Board acceded to the request of the firm for import of already registered products Requip PD Tablet 2mg vide Reg. No. 094747, Requip PD Tablet 4mg vide Reg. No. 094748, Requip PD Tablet 8mg vide Reg. No. 094749 in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at M/S Glaxosmithkline Pakistan Limited, F-268, SITE, Karachi DML No.000233 to comply requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) years only.**

Case No.70: CORRECTION OF PRODUCT NAME OF M/S. HIMMEL PHARMACEUTICALS (PVT) LTD. LAHORE.

Registration Board in its 287th meeting approved the following products of M/s. Himmel Pharmaceuticals (Pvt) Ltd, 793-D, Block-C, Faisal Town, Lahore for change of manufacturing site of their already registered products.

The product names as per initial registration letters are Oxaliplatin LIV Pharma whereas as per submitted documents by the firm the products name is different i.e. Oxaliplatin AqVida. Details are as under: -

S. No	Reg. No.	Name & Composition (as per initial letter)	Name & Composition As per COPP, Form-5A & letter of Authorization from AqVida GmbH
1.	085251	Oxaliplatin LIV Pharma 50mg/10ml Concentrate for solution for IV Infusion Each ml contains: - Oxaliplatin….5mg	Oxaliplatin AqVida 50mg/10ml Concentrate for solution for IV Infusion Each ml contains: - Oxaliplatin….5mg

2.	084810	Oxaliplatin LIV Pharma 100mg/20ml Concentrate for solution for IV Infusion. Each ml contains: - Oxaliplatin….5mg	Oxaliplatin AqVida 100mg/20ml Concentrate for solution for IV Infusion. Each ml contains: - Oxaliplatin….5mg

Accordingly, the correct/ ammended product name according to submitted legalized & attested documents by M/s. Himmel Pharmaceuticals (Pvt) Ltd, 793-D, Block-C, Faisal Town, Lahore has been granted.

Decision: Registration Board noted the information.

Case No.71: REQUEST OF M/S. ABBOTT LABORATORIES (PAKISTAN) LIMITED, KARACHI FOR REGISTRATION OF DRUGS.

M/s. Abbott Laboratories (Pakistan) Limited, Karachi has submitted an application for Registrations of following products from M/s Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi. Detail of each proposed product is as under:

Product-1: Dermofix Cream 30gm (Reg.No.014083)		
S. No.	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Dermofix Cream 30gm Each gm contains:- Sertaconazole nitrate...20mg
2.	Name and address of Applicant (transferee)	M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.
3.	Name of Transferor	M/s Alina Combine Pharmaceuticals (Pvt) Ltd, 208, Amber Estate, Shahrah-e-Faisal, Block 7-8, Karachi
4.	Detail of Drug Sale License	Address: M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.
5.	Name and address of manufacturer.	**As per approval:-** M/s. Ferrer Pharma International S.A., Barcelona, Spain. **As per Form-5A & COPP:-** M/s. Ferrer Internacional, S.A. Joan buscalla 1-9, 08173 Sant Cugat del Valles (Barcelona) Spain.
6.	Name and address of product license holder (as per COPP)	M/s. Ferrer Internacional, S.A. Gran Via Carlos III, 94 08028 Barcelona Spain.
7.	Name of exporting country	Spain
8.	Diary No. & Date of R& I	Dy. No. Nil Dated 18/08/2013, Dy. No. 32850 Dated 02/10/2018 & Dy. No. 243 Dated 11/03/2019
9.	Finished Product Specification	-
10.	Shelf life	3 Years (as per Form-5A)
11.	Pack Size	30gm (as per approval)
12.	**Remarks: -**	

Product-2: Somazina Drops 30ml (Reg.No. 016974)		
S. No.	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**As per Approval** Somazina Drops 30ml Each 100ml contains: CDP-choline sodium eq. to 10gm of CDP-Choline.

		As per COPP Each ml contains: Citicoline…….100mg.
2.	Name and address of Applicant (transferee)	M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.
3.	Name of Transferor	M/s Alina Combine Pharmaceuticals (Pvt) Ltd, 208, Amber Estate, Shahrah-e-Faisal, Block 7-8, Karachi
4.	Detail of Drug Sale License	Address: M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.
5.	Name and address of manufacturer	**As per approval:-** M/s. Ferrer International S.A., Spain. **As per Form-5A & COPP:-** M/s. Ferrer Internacional, S.A. Joan buscalla 1-9, 08173 Sant Cugat del Valles (Barcelona) Spain.
6.	Name and address of product license holder	M/s. Ferrer Internacional, S.A. Gran Via Carlos III, 94 08028 Barcelona Spain.
7.	Name of exporting country	Spain
8.	Diary No. & Date of R& I	Dy. No. nil Dated 18/08/2013, Dy. No. 32850 Dated 02/10/2018 & Dy. No. 243 Dated 11/03/2019
9.	Finished Product Specification	-
10.	Shelf life	3 Years (as per Form-5A)
11.	Pack Size	30ml (as per approval)
12.	**Remarks:** -	

Product-3: Somazina 500 Injection (Reg.No. 016975)

Name / detail of documents	**Documents / information provided by firm**
Product Name / Composition	**As per approval** Somazina 500 Injection Each ampoule contains: Cytidine 5 diphosphate choline, sodium salt (100%) eq to 500mg cytidine 5 diphosphate choline. **As per COPP** Each ampoule contains: Citicoline…….500mg.
Name and address of Applicant (transferee)	M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.
Name of Transferor	M/s Alina Combine Pharmaceuticals (Pvt) Ltd, 208, Amber Estate, Shahrah-e-Faisal, Block 7-8, Karachi
Detail of Drug Sale License	Address: M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi.
Name and address of manufacturer	**As per approval:-** M/s. Ferrer International S.A., Spain. **As per Form-5A & COPP:-** M/s. Ferrer Internacional, S.A. Joan buscalla 1-9, 08173 Sant Cugat del Valles (Barcelona) Spain.
Name and address of product license holder	M/s. Ferrer Internacional, S.A. Gran Via Carlos III, 94 08028 Barcelona Spain.
Name of exporting country	Spain
Diary No. & Date of R& I	Dy. No. nil Dated 18/08/2013, Dy. No. 32850 Dated 02/10/2018 & Dy. No. 243 Dated 11/03/2019
Finished Product Specification	-
Shelf life	3 Years (as per Form-5A)

Pack Size	Box of 5 ampoules (as per approval)
Remarks: -	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Fee of Rs.300,000/- (100,000/- for each product).
b) Applications on Form-5A.
c) Registration letters with complete renewal status.
d) Original legalized CoPP (fresh).
e) Fresh NOC for transfer of registrations by M/s Alina Combine (Pakistan) Ltd (issued on 03-08-2018).
f) Cancellation of agreement with previous distributor (M/s Alina Combine (Pakistan) Ltd) and appointment as sole distributor for above product (M/s Abbott Laboratories (Pakistan) Limited, Karachi).

Decision:- Keeping in view the above position, Registration Board decided as follows;

a. Approved the cancellation of registration of Dermofix Cream 30gm (Reg.No.014083) from the name of M/s Alina Combine Pharmaceuticals (Pvt) Ltd, 208, Amber Estate, Shahrah-e-Faisal, Block 7-8, Karachi.
b. Approved the registration of Dermofix Cream 30gm in the name of M/s. Abbott Laboratories (Pakistan) Limited, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).
c. A reference of Dermofix Cream 30gm (Reg.No.014083) shall be sent to Costing & Pricing Division for their comments regarding MRP of the said product.
d. Deferred the products "Somazina Drops 30ml (Reg.No. 016974) & Somazina 500 Injection (Reg.No. 016975) for the clarification regarding the difference in composition as per approval letter and COPP from the applicant.

Case No.72: REQUEST OF M/S SERVIER RESEARCH AND PHARMACEUTICALS (PAKISTAN) (PVT) LTD, LAHORE FOR CHANGE OF SITE OF REGISTERED DRUGS.

M/s Servier Research and Pharmaceuticals (Pakistan) (Pvt) Ltd, 65 Main Boulevard, Gulberg, Lahore, has applied for change of Primary & Secondary Packaging, QP release site of their following already registered products as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter)	Existing approved site (as per approval letter)	New Proposed Site / Manufacturer / Product License Holder (as per COPP)
1.	094762	Lonsurf 15mg Tablet Each film coated tablet contains: Trifluridine….. 15mg Tipiracil HCl…… 7.065mg (eq. to Tipiracil….. 6.14mg) (As per Innovator's Specifications*)	**Manufacturer:** a. M/s Taiho Pharmaceutical Co.,ltd., Kitajima Plant, 1-1, Iuchi, Takabo, Kitajima-cho, Itano-gun,771-0206, Tokushima, Japan (Site responsible for manufacturing) b. M/s AndersonBrecon (UK) Limited, Units 2-7, Wye Valley Business Park, Brecon Road, Hay-On-Wye, HR3 5PG Hereford, United Kingdom (Site	**Manufacturer:** M/s Les Laboratoires Servier Industrie (LSI) 905, ROUTE DE Saran, 45520 Gidy, France. (Site responsible for Quality Control, Secondary packaging and also primary packaging) **Product License Holder:-** M/s Les Laboratoires

			responsible for quality control) c. M/s AndersonBrecon (UK) Limited, Unit 1, Talgarth Business Park, Trefecca Road, Talgarth, Brecon, LD3 0PQ Powys, United Kingdom (Site responsible for primary and secondary packaging) **Product License Holder:-** M/s Les Laboratoires Servier, 50 rue Carnot, 92284 Suresnes Cedex, France	Servier, 50 rue Carnot, 92284 Suresnes Cedex, France
2.	090527	Lonsurf 20mg Tablet Each film coated tablet contains: Trifluridine….. 20mg Tipiracil HCl…… 9.420mg (eq. to Tipiracil….. 8.19mg) (As per Innovator's Specifications*)	-do-	-do-

2. The firm has submitted the following supporting documents: -
   a) Fee of Rs.200,000/-
   b) Application on Form-F
   c) Copy of initial registration letter.
   d) Original & legalized COPP (issued by EMA).
   e) Copy of authorization letter.
   f) Site master file for new manufacturing site.
   g) Undertakings that provided information are correct.

Decision: **Registration Board approved the above changes in respect of registered products Lonsurf 15mg Tablet (Reg.No. 094762) and Lonsurf 20mg Tablet (Reg.No. 090527) subject to policy for imported finished drug registration. Other terms and conditions remain the same.**

Case No.73: REQUEST OF M/S HIMMEL PHARMACEUTICALS (PVT) LTD, LAHORE FOR CHANGE OF SITE OF REGISTERED DRUGS.

M/s Himmel Pharmaceuticals (Pvt) Ltd, 793-D, Block-C, Faisal Town, Lahore has applied for change of manufacturing site of their following already registered products as per details given below:

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 06-06-2017)	Existing approved site (as per approval letter)	New Proposed Site / Manufacturer (as per COPP)
1.	084630	Paclitaxel LIV Pharma 300 mg /50ml concentrate for solution for infusion. Each 50ml contains:- Paclitaxel ……300mg (USP Specifications) **As per COPP/Form-5A& letter of authorization** brand name is Paclitaxel AqVida	**Manufacturer:** M/s. Oncotec Pharma Produktion GmbH, Am Pharmapark, 06861 Dessau-Rosslau, Germany. **Product License Holder:-** M/s. AqVida GmbH, Kaiser-Wilhelm-Str. 89, 20355 Hamburg, Germany	**Name & Address of Manufacturer (as per COPP & Form-5A):-** M/s Aqvida GmbH Werkstr. 21 23942 Dassow, Germany. **Product License Holder:-** M/s. AqVida GmbH, Kaiser-Wilhelm-Str. 89, 20355 Hamburg, Germany.

2.	084631	Paclitaxel LIV Pharma 100 mg / 16.7 ml concentrate for solution for infusion. Each 16.7ml contains:- Paclitaxel ……100mg (USP Specifications) **As per COPP/Form-5A& letter of authorization** brand name is Paclitaxel AqVida	-do-	-do-
3.	084632	Paclitaxel LIV Pharma 30 mg / 5 ml concentrate for solution for infusion. Each 5ml contains:- Paclitaxel ……30mg (USP Specifications) **As per COPP/Form-5A& letter of authorization** brand name is Paclitaxel AqVida	-do-	-do-

2. The firm has submitted the following supporting documents: -

a) Fee of Rs.300,000/- (3x100,000/-).
b) Application on Form 5A (date of application 01-03-2019)
c) Copy of initial registration letters.
d) Original & legalized COPP.
e) Copy of GMP certificate.
f) Copy of authorization letter.
g) Site master file for new manufacturing site.
h) Undertakings that provided information are correct.
i) The firm has changed its brand name from Paclitaxel LIV Pharma to Paclitaxel AqVida.

Decision: **Registration Board approved the above changes in respect of registered products Paclitaxel LIV Pharma 300 mg /50ml concentrate for solution for infusion (Reg.No. 084630), Paclitaxel LIV Pharma 100 mg / 16.7 ml concentrate for solution for infusion. (Reg.No. 084631) and Paclitaxel LIV Pharma 30 mg / 5 ml concentrate for solution for infusion (Reg.No. 084632) subject to policy for imported finished drug registration. Other terms and conditions remain the same. The board has also approved the change in the brand name from Paclitaxel LIV Pharma to Paclitaxel AqVida.**

Case No.74: Correction in Formulation of Registered Drug(s) of M/s. Zafa Pharmaceutical Laboratories, Karachi.

M/s. Zafa Pharmaceuticals Laboratories (Pvt.) Ltd, L-1/B, Block 22, Federal "B" Industrial Area, Karachi-75950 has requested for correction of formulation of following registered product in compliance of WHO approved formulation:-

Sr.#	Reg. No.	Name of Drug (s) with existing formulation	Name of Drug (s) with proposed formulation
1.	022236	**Orazaf Powder** Each sachet contains:- Sodium Chloride …….. 3.5gm Sodium citrate …….. 2.9gm Potassium Chloride ….. 1.5gm Dextrose Anhydrous … 20gm (Flavour Orange / Lemmon)	**Orazaf Powder** Each sachet contains:- Sodium Chloride …….. **2.6gm** Potassium Chloride ….. 1.5gm Sodium citrate …….. 2.9gm Glucose Anhydrous..…. 20gm **Remarks:** As per WHO approved formulation, Glucose Anhydrous is 13.5gm.

- The firm has submitted the following documents.

Sr.#	Requirement as per SOP	Submission
1.	Application with required fee as per relevant SRO.	Rs.25,000/- Fee.
2.	Copy of registration letter and last renewal status.	Submitted. (DOR: 09-03-18)
3.	Document in support of proposed correction/evidence of approval status by Reference Regulatory Authorities/ innovator product and/or Pharmacopeias as adopted by Registration Board.	Provided WHO reference for this purpose.
4.	Undertaking that the provided information/ documents are true/ correct.	Submitted.

The Committee in its 14th meeting deferred the case for provision of fee of Rs. 20,000/-; Form-5 and presentation before Registration Board.

The management of the firm has deposited fee of Rs. 20,000/- for this purpose and provided WHO reference for this purpose.

Decision of 19th PRVC:

"The Committee referred the case to Registration Board".

"Decision of 287th Meeting of Registration Board:

Registration Board deferred the case for confirmation of renewal status from RRR section".

Remarks: Now, the RRR Section of has confirmed that the firm has submitted the application within due time.

Decision: Registration Board deferred the request of firm for clarification of applied formulation regarding quantity of glucose anhydrous.

Case No.75: Correction in Formulation of Drug(s) of M/s. Maxitech Pharma (Pvt.) Ltd; Karachi.

M/s. Maxitech Pharma (Pvt.) Ltd., Plot No. E-178, SITE, Karachi have requested for correction in formulation of their following already registered product. The details are as under:

Sr.#	Reg. No.	Existing name with composition / Specifications	Correction required in composition / Specification
1.	085964	**Fusimax 2% Oinment** Each gm contains:- Fusidic Acid …….…… 2% (As per *Innovator's Specification)	**Fusimax 2% Oinment** Each gm contains:- **Sodium Fusidate ……..…. 2%** (As per *Innovator's Specification)

- The firm has submitted the following documents.

Sr.#	Requirement as per SOP	Submission
i.	Application with required fee as per relevant SRO.	Rs.5,000/- alongwith Form-5.
ii.	Copy of registration letter and last renewal status.	Submitted. (DOR: 13-12-17) Validity confirmed from RRR.
iii.	Document in support of proposed correction/evidence of approval status by Reference Regulatory Authorities/ innovator product and/or Pharmacopeias as adopted by Registration Board.	Evidence of approval status by Reference Regulatory Authorities **Provided.**
iv.	Undertaking that the provided information/ documents are true/ correct.	**Provided**

"Decision of 19th PRVC:

The Committee deferred the case for fee of Rs. 20,000/- alongwith Form-5 and referred the case to Registration Board".

Remarks: Now, the firm has submitted the differential fee of Rs.20,000/- alongwith Form-5.

Decision: Registration Board deferred the request of firm for justification/reason of proposed change in formulation.

Case No.76: Similarity of Brand Names of M/s. Genix Pharma, Karachi.

In the light of decisions of 14th & 25th meetings of PRVC, M/s. Genix Pharma (Pvt.) Ltd, 44, 45-B, Korangi Creek Road, Karachi was advised to change the brand names of their some registered products having close resemblance with already registered drugs. The details of drugs having brand name resemblance are as under;

Sr.#	M/s Genix Pharma Pvt. Ltd, Karachi		Names of firms with products with whom brand name resemble	
	Reg. No.	Name of Drug (s) with composition	Name of Firm	Name of Drug (s) with Composition & Reg. No.
1.	073470	Hylu Eye Drops (Sodium Hyalurate)	M/s Helix Pharma (Pvt.) Ltd, Karachi.	Hylo Eye Drops (Sodium Hyalurate) Reg.No.067031
2.	086947 086949	Nebilol 2.5mg tablet Nebilol 5mg tablet	M/s Tabros Pharma (Pvt.) Ltd, Karachi.	Nebivol 2.5mg Tab.(R.# 061530) Nebivol 5mg Tab. (R.# 061531) Nebivol 10mg Tab. (R.# 061532)

Now, the firm has intimated that **Hylu is their registered Trade Mark** and intend to retain the same brand name in the market.

Further, the firm also intimated that there are many similar brand names in the market for the same generic name and their brand name **Nebilol** is a good-marketed product and established brand name of the firm and intend to retain the same brand name in the market.

"Decision of 27-PRVC Meeting:

The Committee referred the case to Registration Board".

Decision: **Registration Board decided to write final reminder to M/s. Genix Pharma (Pvt.) Ltd, 44, 45-B, Korangi Creek Road, Karachi for submitting alternate brand names. Incase of non-compliance case shall be placed before Registration Board in the light of decision of 242nd meeting.**

Case No.77: Change of Title of Manufacturer of Products of M/s Sanofi-aventis Pakistan Ltd, Karachi.

M/s Sanofi has requested for change of title of Manufacturer of their following registered products as per details below;

Sr.#	Reg. No.	Product Name & composition	Present Manufacturing Title	Proposed Manufacturing Title	Remarks
	019567	Amaryl 1mg tablet	Sanofi-aventis S.p.A. S.S. 17 KM 22– 67019 Scoppito (AQ), Italy.	Sanofi S.p.A. S.S. 17 KM 22– 67019 Scoppito (AQ), Italy.	Manufacturing site remains same.
	019568	Amaryl 2mg tablet			
	021094	Amaryl 3mg tablet			
	021095	Amaryl 4mg tablet			

The firm has submitted the following docucments;

Sr.#	Documents as per SOP	Submission
a.	Application with required fee as per relevant SRO.	Rs.5,000/- for each product **Provided**
b.	Copy of registration letter and last renewal **date**	**Provided**
c.	Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name Or Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin Or any legalized document of concerned regulatory authority confirming change of name of Manufacturer/ Marketing Authorization Holder without change in manufacturing site.	**Provided**
e.	Undertaking that the provided information/ documents are true/ correct.	**Provided**

Decision: **Registration Board acceded to firm's request for change in title/name of manufacturer from Sanofi Aventis, Italy to Sanofi, Italy (manufacturing site remain same)**

Case No.78: Change of Title of Manufacturer of Products of M/s Le Mendoza Pharmaceuticals (Pvt.) Ltd, Karachi.

The title of the firm has been changed from M/s. Chas .A. Mendoza (DML No. 000140) to M/s. Le Mendoza Pharmaceuticals (Pvt.) Ltd., Karachi vide letter no. F.6-1/2013-Lic (M-232) dated 2nd September, 2013. The firm applied on 26-04-2014 for transfer of registration of following products due to change in the Company Name/Title Name from M/s Chas. A Mendoza Karachi to M/s Le Mendoza Pharmaceutical (Pvt) Ltd Karachi, where the DML and site remains the same and case was considered in the 263rd meeting of Registration Board. The Board decided to send the RRR section for verification of Renewal status as per decision of the Board. However, as there is only change of title of the firm and renewal status of the various products of the firm needed validation. Subsequently, firm has applied vide S.R.O 1005(I)/2017 and submitted the three times renewal fee for each product, whose renewal has been expired in previous years.

Sr. No.	Reg. No.	Name of product along with composition	Initial Date of Reg.	Fee along with date	Remarks	Renewal validity till
7	055660	Kilcam Dry Suspension Each 5 ml contain Clarithromycin … 125mg	03/04/2009 Change of brand name dated 29/08/2009	(Due date: 28-08-2014) Rs.30,000/- 04-12-2017	Locally Manufactured	28-08-2019

Decision of 277th Meeting:
Registration Board deferred the product for submission of legalized source of clarithromycin.

Now, the firm has submitted the Legalized source of clarithromycin Stability Data, cGMP (dated 28-Mar-2018) by M/s Surge Laboratories (Pvt.) Ltd, 10 KM Faisalabad road, Bikhi District Sheikhupura.

Decision: Registration Board acceded to firm's request for change in title/name of manufacturer from M/s. Chas .A. Mendoza to M/s. Le Mendoza Pharmaceuticals (manufacturing site remain same)

Case No.79: Change of Address of Manufacturing Site of 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 of M-288th Meeting:

Registration Board deferred for confirmation whether case pertains to change in address or manufacturing site".

Fresh Submission:
Firm Submitted documents clarifying that manufacturing site of manufacturer i.e. **Changzhou Siyo Pharmaceuticals Co, Ltd**. has been changed as follows;

From: Meilongba, Southern Suberb, Changzhou, Jiangsu, China
To: No.567 Zhongwu Avenue, Changzhou, Jiangsu, China.

Decision: Registration Board acceded to firm's request for change in address of manufacturer i.e. Changzhou Siyo Pharmaceuticals Co, Ltd. Site inspection shall be conducted as per Import Policy for Finished Drugs.

Case No.80: Change of Registration Status from Import to Local Manufacturing by M/s Abbott Laboratories (Pakistan) Ltd, Karachi.

M/s Abbott Laboratories (Pakistan) Ltd, Karachi have requested for transfer of their following registered product from finished import to local manufacturing. The details are as under;

Sr. No.	Reg. No	Name of Drug(s) & Composition	Existing Manufacturer	Proposed Source of Manufacturer of Pellets	Proposed Formulation and repacking site
1	009192	**Froben SR Capsule** Each capsule contains: Flurbiprofen sustained release pellets…200mg	M/s. Famar, L'Aigle, France	Alphamed Formulaitons Pvt. Ltd. Sy. No.225, Sampanbole Village Shamirpet Mandal, Medchal –Malkargiri District Telangana-500078, India.	M/s Abbott Laboratories (Pakistan) Ltd, Opposite Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi

The firm has submitted following documents:

1. Fee of Rs. 100,000/- deposited.
2. Application on Form-5.
3. Copy of initial registration (28-Jul-1986) letter and renewal confirmed from RRR Section.
4. cGMP of Pellets Manufacturing Site (Valid till 08-May-2020).
5. Stability Data of Pellets (Zone IV-A) Real & Accelerate time.
6. Certificate of Analysis of Pellets.
7. Undertaking regarding impact of Shelf life.

Decision: Registration Board deferred the request of firm for NOC of marketing authorization holder / manufacturer.

Case No.81: Termination of Contract Manufacturing and Registration of Drugs for Manufacture in 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 products 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:

S.#	Reg.No.	Name of Drug (s) and Composition	International Availability
1.	019464	**Brevoxyl Cream** Each gm contains: Benzoyl peroxide……...4 %	Approved by MHRA, UK Brevoxyl 4 % Cream by GSK Consumer Healthcare

2.	043657	**Clinagel** Each gm contains: Clindamycin phosphate……...10mg	Approved by US FDA, CLINDAGEL 1 % by Precision Dermat
3.	019738	**Lacticare 1% Lotion** Each gm contains: Hydrocortisone……..…...1.06%	Approved by US FDA, ACTICORT 1 % Lotion by Baker Norton (Marketing status Discontinued)
4.	019739	**Lacticare 2.5% Lotion** Each gm contains: Hydrocortisone……..…2.5%	US FDA, ALA-SCALP **2 %** Lotion by Crown Labs
5.	005039	**Lacticare Lotion** Each gm contains: Sodium pyrrolidone Carboxylate….2.75% Lactic acid……...…..5.70%	Evidence of approval in Reference regulatory authorities required from the firm
6.	024757	**Stiemazole Lotion** Each gm contains: Clotrimazole……...1%	MHRA, UK Canestene 1 % w/v Solution by Byer plc
7.	048074	**Stieproxal Liquid** Each gm contains: Ciclopiroxolamine……..15mg Salicylic acid……..…30mg	Evidence of approval in Reference regulatory authorities required from the firm
8.	026392	**Stieprox Liquid** Each gm contains: Cyclopirox Olamine…….1.500%	Approved in Health Canada

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 30.6.2020. The firm has provided following documents in support to:

i. Request with Rs. 20,000/- for each product.
ii. Form-5
iii. Last contract manufacturing permission with M/s Akhai Pharma, Karachi.
iv. Stability Data.
v. Last Inspection report dated 10.08.2017.
vi. Initial registration letter.
vii. Transfer of registration from M/s Stiefel Laboratories Pakistan (Pvt.) Ltd., Lahore
viii. Section approval dated 09.06.2015
ix. NOC for CRF dated 17.05.2017 valid up to 30.06.2018.

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.

The firm has now requested for reconsideration of above request.

Decision of M-287:

"Registration Board deferred the case for submission of fresh application along-with requisite fee for each product."

Fresh Submission:

Now, the firm has submitted fresh application; fee of Rs.20,000/- for each product alongwith the Inspection Report of M/s GSK Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi dated 12th December, 2018 and requested for reconsideration of above request.

Decision: **Registration Board acceded to firm's request for termination of contract manufacturing and granted permission to M/s GSK Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi for manufacturing of above mentioned products at their own site.**

Case No.82: Change of Title of Contract Manufacturer of Registered Drug(s) of M/s Novartis Pharma (Pakistan) Limited, Karachi.

M/s Novartis Pharma (Pakistan) Limited, 15-West Wharf, Dockyard Road, Karachi has requested to grant registration with new title of contract manufacturer from **M/s GlaxoSmithKline OTC (Pvt.) Limited to M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited, Petaro Road, Jamshoro** (site remains the same) of their following registered products;

Sr.#	Reg. No.	Name of Drug(s)	Existing name of Manufacturer	Proposed Name of Manufacturer
1.	024660	Annuva Dispersible Tablets Each dispersible tablet contain Diclofenac acid	M/s GlaxoSmithKline OTC (Pvt.) Limited, Petaro Road, Jamshoro	M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited, Petaro Road, Jamshoro.
2.	021528	Caflam 50mg Tablets Diclofenac potassium…50mg		
3.	013208	Lamisil 150mg Tablets Terbinafine…….150mg		
4.	013209	Lamisil 250mg Tablets Terbinafine…….250mg		
5.	007823	Mepresor 100mg Tablets Metoprolol…….100mg		
6.	036125	Mepresor SR 200mg Tablets Each sustained release tablet contain: Metoprolol tartrate…..200mg		
7.	001576	Methergin Sugar Coated Tablet Each sugar coated tablet contains Metoprolol,,,,,,,100mg		
8.	006144	Mosegor Sugar Coated Tablets Pizotifen…….0.5mg		
9.	006282	Mosegor Syrup Pizotifen…….0.25mg		
10.	021529	Tegral 200mg Tablets Carbamazepine…..200mg		
11.	070803	Tegral Suspension Each 5ml contain Carbamazepin……100mg		
12.	041184	Trioptal 300mg tablet Each film coated tablet contain Oxcarbazepin……300mg		
13.	041185	Trioptal 600mg tablet Each film coated tablet contain Oxcarbazepin……600mg		
14.	021524	Voltral 25mg Tablets Diclofenac sodium….25mg		
15.	021525	Voltral 50mg Tablets Diclofenac sodium….50mg		
16.	021526	Voltral SR 100mg tablet Diclofenac sodium….100mg		
17.	018615	Axcin 250mg Tablets Ciprofloxacin HCl eq.to		

		ciprofloxacin…….250mg		
18.	018616	Axcin 500mg Tablets Ciprofloxacin HCl eq.to ciprofloxacin…….500mg		
19.	**045415**	**Azomax 500mg Capsules** **Azithromycin…500mg**		
20.	**022200**	**Azomax 250mg Capsule** **Azithromycin…250mg**		
21.	**022201**	**Azomax 200mg oral suspension** **Each 5ml contain** **Azithromycin…..200mg**		
22.	007820	Clomfranil 10mg Tablets Clomipramine hydrochloride….10mg		
23.	007821	Clomfranil 25mg Tablets Clomipramine hydrochloride….25mg		
24.	007533	Dermazin Cream 1% Each gram contain Silver sulphadiazine…10mg		
25.	048407	Glory 1mg Tablets Glimepride….1mg		
26.	048408	Glory 2mg Tablets Glimepride….2mg		
27.	048409	Glory 3mg Tablets Glimepride….3mg		
28.	048410	Glory 4mg Tablets Glimepride….4mg		
29.	018063	Nocid 20mg Tablets Famotidine…..20mg		
30.	018064	Nocid 40mg Tablets Famotidine…….40mg		
31.	004714	Parlodel Tablets		
32.	023372	Quvasc 2.5mg Tablets Amlodipine Besylate…..2.5mg		
33.	023373	Quvasc 5mg Tablets Amlodipine Besylate…..5mg		
34.	023374	Quvasc 10mg Tablets Amlodipine Besylate…..10mg		
35.	021521	Rimactal Syrup Each 100ml contain Rifampicin…..2g		
36.	014316	Ternelin 2mg Tablets Tizanidine HCl…..2mg		
37.	014315	Ternelin 4mg Tablets Tizanidine HCl…..4mg		
38.	005804	Zatofen Syrup		
39.	005642	Zatofen Tablets Each film coated tablet contain Ketotifen(as hydrogen fumarate) ……..1mg		

The firm has submitted the following documents;

Sr.#	Requirement as per SOP	Submission
i.	**a)** Application on Form-5 with required fee as per relevant SRO.	Form-5; with Rs.50,000/- each.
ii.	**b)** Copy of registration letter and last renewal status.	**Provided.**
iii.	**c)** Approval of new name / title from CLB.	Copy of DML, CRF & approval of M/s GSK Consumer Healthcare Pakistan

		Ltd, Petaro Road Jamshoro.
iv.	**d)** Undertaking that: **i.** The formulation, API source & Specifications, manufacturing process, release & shelf life specifications have not changed. **ii.** Provided information is true & correct.	Undertaking by M/s Novartis Pharma Pakistan Ltd, Karachi.

Decision: **Registration Board acceded to firm's request for change in title of contract manufacturer of above mentioned products from M/s GlaxoSmithKline OTC (Pvt.) Limited, Petaro Road, Jamshoro to M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited, Petaro Road, Jamshoro (manufacturing site remains same).**

Case No.83: Change of Name of Manufacturer of Bulk Import & Local Repackaging Products of M/s Martin Dow Limited, Karachi.

M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi importing the following registered products manufactured by M/s Roche S.p. A.Segrate, Italy;

Sr.#	Reg. No.	Name of Product with specification	Existing name of manufacturer/QC release site	Product license holder
1.	022988	**Dilatrend 6.25mg Tablet** Each tablet contains: Carvedilol……..6.25mg	M/s Roche S.p. A.Segrate, Italy	Cheplapharm Arzneimittel GmbH Ziegelhof 24, 17489 Greifswald Germany
2.	022989	**Dilatrend 12.5mg Tablet** Each tablet contains: Carvedilol……..12.5mg		
3.	017005	**Dilatrend 25mg Tablet** Each tablet contains: Carvedilol……..25mg		

Now, the firm has requested for the change of name of manufacturer of above products from **M/s Roche S.p. A.Segrate, Italy** to **M/s Delpharm Milano S.R.L 20090–Segrate (MI), Italy**; however, the **manufacturing site will remain the same**.

In this regard, the firm has submitted the following documents;

i. Fee of Rs.5,000/- for each product.
ii. Copy of registration letters & Renewal confirmed from RRR Section vide letter No.F.3-8/2018-RRR (M-286) dated 12-February-2019.
iii. Copy of NOC for CRF.
iv. Original & legalized CoPP.
v. Original & legalized GMP Certificate.
vi. Original & legalized manufacturing authorization certificate.
vii. Original & Legalized Agency Agreement b/w M/s Martin Dow Ltd, Karachi & the Product Licensed Holder M/s Chepla Pharm, Germany.

Decision of 25th Meeting of PRVC:

"The Committee referred the case to Registration Board".

Since title of importer is also changed from M/s Martin Dow Pharmaceutical Limited, Karachi to Martin Dow Limited, Karachi. Hence firm requested grant registration with new title i.e. M/s Martin Dow Limited, Karachi. Firm has also submitted fee of Rs 100,000/- for each product.

Decision: **Registration Board acceded to firm's request for change in title of manufacturer of above mentioned products from M/s Roche S.p. A.Segrate, Italy to M/s Delpharm Milano S.R.L 20090–Segrate (MI), Italy (manufacturing site remains same) and change in title of importer from M/s Martin Dow Pharmaceutical Limited, Karachi to Martin Dow Limited, Karachi**

Case No. 84: Request for Post Registration Variations in Registered Product of M/s Martin Dow Ltd, 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	Date with Dy. No. and fee
01.	042142	**Xenical Capsule 120mg** Each capsule contains: Orlistat……..…120mg	10-12-2018 Dy. 2506 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 and last renewal status (application 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 the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.

Decision of 288th Meeting:

"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".

Fresh Submission:

Now, the firm has submitted the following Original Legalized & Notarized Agreement between;

i. Cheplapharm-Arzneimittel GmbH-Germany and Delpharm Milano S.R.L. Italy.
ii. Cheplapharm-Arzneimittel GmbH-Germany and Martin Dow Limited, Karachi.
iii. Fee of Rs 80000/- dated 14-05-2019 for extension in permission for bulk import and local repackaging.

Decision: Registration Board acceded to firm's request for:

1) **Change in title of manufacturer of above mentioned products from M/s Roche S.p. A.Segrate, Italy to M/s Delpharm Milano S.R.L 20090–Segrate (MI), Italy (manufacturing site remains same)**
2) **change in title of importer from M/s Martin Dow Pharmaceutical Limited, Karachi to Martin Dow Limited, Karachi (site remains same)**
3) **Change in license holder from F.Hoffmann La Roche Ltd, Basel, Switzerland to Cheplapharm Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald-Germany.**
4) **Permission for bulk import and local repackaging shall valid till 20.12.2020.**

Case No.85: Change of Contract Manufacturer of Registered Drug(s) of M/s Lawari International, Valley Road, Saidu Sharif, Swat.

M/s Lawari International, Valley Road Sherari, Gulkada, Saidu Sharif, Swat has requested for the change of Name of contract manufacturing from **M/s Bio-Labs (Pvt.) Ltd, Islamabad to M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad** along-with the change of brand names of their following registered products being manufactured by M/s Bio-labs (Pvt) Ltd, Islamabad. The details are as under;

Sr.#	Reg. No.	Name of Drug(s) with composition	Name of Existing Manufacturer	Proposed Name of Manufacturer
1.	056682	**Glifix 400mg Capsules** Each capsule contains: Cefixime Trihydrate=Cefixime ……...400mg (USP Specifications)	M/s Bio-Labs (Pvt.) Ltd, Islamabad	M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad
2.	056683	**Glifix 100mg Suspension** Each 5ml contains: Cefixime Trihydrate=Cefixime ……100mg (USP Specifications)		
3.	056684	**Glifix 200mg Suspension** Each 5ml contains: Cefixime Trihydrate=Cefixime… ……200mg (USP Specifications)		
4.	056685	**Spiro 250mg Injection (IV)** Each vial contains: Ceftriaxone Sodium= Ceftriaxone ……250mg (USP Specifications)		
5.	056686	**Spiro 500mg Injection (IV)** Each vial contains: Ceftriaxone Sodium= Ceftriaxone …....500mg (USP Specifications)		

6.	056687	**Spiro 1gm Injection (IV)** Each vial contains: Ceftriaxone Sodium= Ceftriaxone ……..1gm (USP Specifications)		
7.	073208	**Trize 500mg Injection (IM)** Each vial contains: Ceftriaxone Sodium= Ceftriaxone ……500mg (USP Specifications)		
8.	073209	**Trize 1gm Injection (IM)** Each vial contains: Ceftriaxone Sodium= Ceftriaxone ……..1gm (USP Specifications)		

The firm has submitted the following documents;

i. Fee of Rs.50,000/- for each product submitted on 04-March-2019.
ii. Applications on Form-5.
iii. Contract manufacturing permission valid till **30-Jun-2020.**
iv. Copy of DML, CRF, Section approval & Last inspection Report dated **13-February-2019** of M/s EG Pharmaceuticals, Islamabad.
v. Contract Agreement b/w M/s Lawari Int. Swat & M/s EG Pharmaceuticals, Islamabad dated **28-February-2019**.
vi. Undertaking by M/s EG Pharmaceuticals, Islamabad.

Decision: **Registration Board acceded to firm's request for change in contract manufacturer from M/s Bio-Labs (Pvt.) Ltd, Islamabad to M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad**

Case No.86: De-Registration of Drug (s) by M/s GlaxoSmithKline Pakistan Limited, Karachi.

M/s GlaxoSmithKline Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi has requested for cancellation/De-registration of their following products due to no demand of the products in the market. The details are as under;

Sr.#	Reg.No.	Name Drug with composition	Date of Initial Registration with Renewal Status	Alternate Products
1.	055019	**Valuprazole Capsule** Each capsule contains: Omeprazole (as Pellets) …20mg **Source of Pellets:** M/s Dr.Reddy's Laboratoreis Ltd, India	DOR: 16-Jan-2009 1st Renewal Application: 23-Dec-2013	Ruling of M/s High-Q. Relevole of M/s Pfizer Risek of M/s Getz Pharma Sante of M/s Macter Int.
2.	013816	**Monopril 10mg Tablet** Each tablet contains: Fosinopril Sodium……..10mg	DOR: 17-Nov-1992 Last Renewal Application: 17-Sep-2015	Aksopril of M/s Akson Pharma.

The firm has submitted the following documents;

Sr.#	Requirement as per SOP	Submission
i.	Application with justification.	Provided.
ii.	Copy of registration letter and last renewal status.	Provided.
iii.	List of alternatives brands/ FPPs available in the country.	Provided.
iv.	An undertaking that: **i.** No case is pending at any forum / court of law regarding this product. **ii.** Provided information/ documents are true/ correct.	Provided.

Decision: Registration Board decided as follows:

- **Acceded to firm's request for deregistration of registration of product at Sr. No. 1.**
- **Deferred product at Sr. No. 2 for confirmation of availability status of alternate product.**

Case No.87: De-Registration of Drug (s) of M/s OBS Pakistan Limited, Karachi.

M/s OBS Pakistan Limited, C-14, Manghopir Road, S.I.T.E. Karachi has requested for cancellation/De-registration of their following product due to no demand of the products in the market. The details are as under;

Sr.#	Reg. No.	Name Drug with composition	Date of Initial Registration with Renewal Status	Alternate Products
1.	011019	**Mevacor 20mg tablets** Each tablet contains: Lovastatin……20mg	Initial DOR: 16-May-1990. Transfer of Registration: 09-Jul-2009 Last Renewal:16-Jun-2014	Colostin tablet of M/s Zafa Lovestan of M/s Opal Lab. Lo-Lipid of M/s Nabiqasim Cholescor of M/s Atco Lab.

The firm has submitted the following documents;

Sr.#	Requirement as per SOP	Submission
i.	Application with justification.	Provided.
ii.	Copy of registration letter and last renewal status.	Provided.
iii.	List of alternatives brands/ FPPs available in the country.	Provided.
iv.	An undertaking that: **i.** No case is pending at any forum / court of law regarding this product. **ii.** Provided information/ documents are true/ correct.	Provided.

Decision: Registration Board deferred the request of firm for confirmation of availability status of alternate products of above mentioned formulation.

Case No.88: Discontinuation of Production of Marketed Drug(s) of M/s. Getz Pakistan (Pvt.) Ltd; Karachi.

M/s. Getz Pharma (Pvt.) Ltd; 29-30/27, Korangi Industrial Area Karachi-74900 has informed that they are no more interested to continue the production of following marketed products as there are so many alternate salts are available in the market:-

Sr.#	*Reg. No.*	*Name of Drug(s)*	*Alternate brand*
1.	070450	**Emrix-SR 15 mg Capsule** Each capsule contains:- Each extended release capsule contains:- Cyclobenzaprine HCl as extended release pellets…… 15mg	**Mezrel XR by Pharmevo**
2.	070451	**Emrix-SR 30 mg Capsule** Each capsule contains:- Each extended release capsule contains:- Cyclobenzaprine HCl as extended release pellets ……..… 30mg	**Mezrel XR by Pharmevo**

Remarks: They have submitted it for information of the Registration Board.

"Decision of 19th PRVC:

The Committee referred the case to Registration Board".

Decision: **Registration Board deferred the request of firm for confirmation of availability status of alternate products of above mentioned formulations.**

Case No.89: Correction in Brand Name of Drug(s) of M/s. Faas Pharmaceutical (Pvt.) Ltd; Karachi.

M/s. Faas Pharmaceutical (Pvt.) Ltd; Karachi had requested for change of brand name of their already registered drug(s). The details are as under: -

S.#	Regn. No.	Existing Brand Name	Initial registration with renewal status
1.	085943	**Ulciloc Insta 20mg Sachet** Each sachet contains:- Omeprazole ……...20mg Sodium Bicarbonate …… 1680mg (As per *Innovator's Specification)	Initial registration dated 18.01.2018
2.	086085	**Ulciloc Insta 40mg Sachet** Each sachet contains:- Omeprazole ……...40mg Sodium Bicarbonate …… 1680mg (As per *Innovator's Specification)	-do-

The firm had submitted fee of Rs. 20,000/- for each product and other documents for this purpose and the PRVC approved the change of brand name from "Ulciloc" to "Tinkit Insta". Now, the firm has informed that they have already been granted the registration of Omeprazole pellets under the brand name Nomizil 40mg & 20mg (Reg.No.082167 & 082168). The firm has requested to correct the brand name as per their first priority name i.e Nomizil Insta instead of Tinkit Insta.

"The PRV-Committee in 9th meeting deferred the case for provision of prescribed fee."

The firm has again requested that they have already been granted the registration of "Nomizil 40mg & 20mg Capsule" (Reg.No.082167 & 082168) and they may be granted the brand name "Nomizil Insta" for uniformity of brand name.

"The Committee in its 14th meeting deferred the case to present in Registration Board."

Decision of 286th Meeting of RB:

"Registration Board deferred the case for submission of requisite fee for change of brand name."

Now, the firm has submitted the fees of Rs.20,000x02=40,000/- for the change of brand name of their above mentioned products.

Decision: **Registration Board acceded to firm's request for change of brand name of above mentioned products from Ulciloc" to Nomizil.**

Case No.90: Show-cause Notice Issued to M/s Pharmatec Pakistan (Pvt.) Ltd., S.I.T.E, Karachi under DML No.000024 for Products of M/s OBS Pakistan, Karachi.

- **Previous History of Case: (OK)**

M/s OBS Pakistan Karachi was served with show cause notice as CLB in its 251st meeting held on 6th December 2017 has considered and deliberated the case of M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, S.I.T.E, Karachi under DML No. 000024 by way of formulation (contract manufacturer) and decided to allow grant of renewal section for sterile Liquid ampoule section with the direction that Registration Board be informed about approval of sterile Liquid ampoule section only. It is pertinent to mention that

hormonal products of M/s OBS Pakistan, Karachi were manufactured by M/s Pharmatec Pakistan by permission vide letter no. F.3-3/2015-Reg-II (M-249) dated 26th August, 2015, i.e., valid for 30-06-2020.

The above stated facts of the case were presented in the 275th meeting of Registration Board. Wherein, it was decided to "issue a show cause notice to M/s OBS Pakistan, Karachi for their hormonal products which were being manufactured by M/s Pharmatec Pakistan (Pvt.) Ltd., Karachi on contract basis."

Accordingly, a show cause was issued to M/s OBS Pakistan (Pvt.) Ltd., Karachi vide letter no. F.3-12/2017-Reg-II (M-275) dated 15.02.2018. Now the firm has submitted the reply which was considered in 280th meeting of registration board. The board considered the reply of the firm and decided to defer the case till decision of Central Licensing Board on application of the firm for contract manufacturing.

Sr. No.	Registration holder	Contract manufacturer	Reg. No.	Name of drug(s) & Composition	Validity of last permission
1.	OBS Pakistan Karachi	M/s Pharmatec Pakistan, Karachi	002444	**Deca – Durabolin 100mg Injection** Each ml amploule contains:- Nandrolone Decanoate … 100mg (As per *Innovator's Specification)	30.06.2020
2.	-do-	-do-	002442	**Deca – Durabolin 25mg Injection** Each ml ampoule contains:- Nandrolone Decanoate …. 25mg (As per *Innovator's Specification)	30.06.2020
3.	-do-	-do-	002443	**Deca – Durabolin 50mg Injection** Each ml ampoule contains:- Nandrolone Decanoate …. 50mg (As per *Innovator's Specification)	30.06.2020
4.	-do-	-do-	002446	**Sustanon 250mg Injection** Each ml contains:- Testosterone Propionate …30mg Testosterone Phenylpropionate…60mg, Testosterone Insocaproate … 60mg Testosterone Decanoate 100mg (As per *Innovator's Specification)	30.06.2020

Then, the firm has submitted applications on Form-5, along with fee of Rs. 50,000/- for each product & other relevant document. M/s. OBS Pakistan (Pvt.) Ltd; and **requested to change the contract manufacturer of above product** from M/s Pharmatec Pakistan, Karachi to M/s. Geofman Pharmaceuticals, 20/23 Main Korangi Industrial Area, Karachi. The case was placed before the Registration Board in its 284th meeting and the board decided as under: -

- **Decision of 284th Meeting:**

  "Registration board deferred the case for confirmation of Liquid Injection (ampoule) Hormone Section from Licensing Division".

Now, the firm has submitted the confirmation from Licensing Division for Injectable (Hormone) Section of M/s. Geofman Pharmaceuticals, 20/23 Main Korangi Industrial Area, Karachi, vide letter No.F.2-11/85-Lic (Pt.) dated 05th March, 2019.

Moreover, the firm has also requested for transfer of Marketing Authorization/ Registration from M/s OBS Pakistan (Pvt.) Ltd, to M/s Aspin Pharma (Pvt.) Ltd, Karachi. In this regard, the firm has also submitted the following documents;

i. Fee of Rs.70,000/- for each product (05-May-2019)

ii. Toll Manufacturing agreement between M/s Aspin & M/s Geofman (02-May-2019)
iii. NOC from M/s OBS Pakistan (Pvt.) Ltd. Karachi for transferring marketing authorization to M/s Aspin Pharma (Pvt.) Ltd, Karachi.
iv. Undertaking from Aspin Pharma that above mentioned formulations are not already registered in their name.

Decision: Registration Board acceded to firm's request for

a) Cancellation of registration of above mentioned products from the name of M/s OBS Pakistan (Pvt.) Ltd. Karachi
b) Grant of registration of above mentioned products in the name of M/s Aspin Pharma (Pvt.) Ltd, Karachi
c) Change of contract manufacturer of above mentioned products from M/s Pharmatec Pakistan (Pvt.) Ltd., S.I.T.E, Karachi to M/s. Geofman Pharmaceuticals, 20/23 Main Korangi Industrial Area, Karachi

Case No.91: Change of Finished Product Specifications/Composition of Registered Drugs by M/s Genix Pharma (Pvt.) Ltd, Karachi.

M/s Genix Pharma (Pvt.) Ltd, 44, 45-K, Korangi Creek Road, Karachi-75190 has requested to change the composition and finished product specifications of their following registered drugs:-

Sr. No	Reg. No.	Name of Drug(s) with existing formulation	Name of Drug(s) with proposed formulation	Proposed Specification
1.	035816 (Last Renewal 01-Dec-14)	Respicare 10mg tablets Each tablet contains: Montelukast Sodium…..10mg	Respicare 10mg tablets Each tablet contains: Montelukast Sodium **equivalent to Montelukast**……..10mg	USP Specification
2.	039039 (Last Renewal 14-May-15)	Respicare 5mg tablets Each tablet contains: Montelukast Sodium…….5mg	Respicare 5mg tablets Each chewable tablet contains: Montelukast Sodium **equivalent to Montelukast** ……..5mg	USP Specification
3.	037534 (Last Renewal 2-Mar-15)	Respicare 4mg Chewable tablets Each tablet contains: Montelukast Sodium…….4mg	Respicare 4mg Chewable tablets Each chewable tablet contains: Montelukast Sodium **equivalent to Montelukast** ……..……4mg	USP Specification

The firm has submitted the following documents;

Sr.#	Requirement as per SOP	Submission
a.	Application with required fee as per relevant SRO.	Rs.5,000/- for each product
b.	Copy of registration letter and last renewal status	Provided
c.	Document in support of proposed change.	Provided
d.	Analytical reports as per monograph of FPP.	Provided
e.	Undertaking that: i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum/court of law regarding this product. iii. 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. iv. The provided information/ documents are true/ correct.	Provided

Decision: **Registration Board acceded to firm's request for correction in formulation and finished product specification of above mentioned products.**

Case No.92: Change of Finished Product Specifications/Composition of Registered Drugs by M/s Atco Laboratories Ltd, Karachi.

M/s Atco Laboratories Ltd, B-18, S.I.T.E., Karachi has requested to change the composition and finished product specifications of their following registered drug:-

Sr. No	Reg. No.	Name of Drug(s) with existing formulation	Name of Drug(s) with proposed formulation	Proposed Specification
1.	035285	Bronkal Respirator Solution Each 100ml contains: Salbutamol (as Sulphate).....**0.5gm** (Last Renewal 20-Nov-14)	Bronkal Respirator Solution Each 5ml contains: Salbutamol (as Sulphate).....**5mg**	BP Specification

The applied formulation exists in British pharmacopeia. According to firm, their registered pack size of 20ml therefore they want to rationalize the label claim with respect of pack size that is 20ml and also standardize the formulation in accordance with the innovator's product i.e. ventoline respirator solution 5mg/5ml (Glaxo Wellcome UK Limited).

The firm has submitted the following documents;

Sr.#	Requirement as per SOP	Submission
a.	Application with required fee as per relevant SRO.	Rs.5,000/- Provided
b.	Copy of registration letter and last renewal status.	Provided
c.	Document in support of proposed change.	Provided
d.	Analytical reports as per monograph of FPP.	
e.	Undertaking that: i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum/court of law regarding this product. iii. 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. iv. The provided information/ documents are true/ correct.	Provided

Decision: **Registration Board deferred request of firm for further review of proposed change in formulation/label claim and differential fee of Rs. 15,000 for this purpose.**

Case No.93. Change of Formulation of Registered Product of M/s Caliph Pharma, Risalpur.

Following case was considered by Registration Board into 283rd meeting as per details below;

Sr. NO.	Reg. No.	Composition & Specifications	Remarks	Proposed Change of Specifications & Corrections
1.	073398	Cepmol Suspension Each 5ml contains: Paracetamol....**125mg** (BP Specification)	The firm wants to standardize its formulation because approved formulation in UK by MHRA is Paracetamol Suspension (Each 5ml containing 120mg of	Cepmol Suspension Each 5ml contains: Paracetamol... **125mg** (BP Specification) **To** Cepmol Suspension

			Paracetamol).	Each 5ml contains: Paracetamol…**120mg** (BP Specification)

Decision of 283rd Meeting:

The Registration Board deferred the product for clarification with regard to availability in reference regulatory authorities.

Fresh Submission:

Now, the firm has submitted the Form-5 alongwith Reference Regulatory Authorities (UK MHRA) for the change of Formulation of the above mentioned product.

Decision: Registration Board acceded to request of firm for change in formulation (125mg/5ml to 120mg/5ml) however reference shall be sent to Cost and Pricing division for MRP confirmation of proposed formulation.

Case No.94: Change of Finished Product Specifications.

The following firms have requested for the change of finished products specifications of their registered drugs;

Sr.#	Requirement as per SOP	Submission
a.	Application with required fee as per relevant SRO.	Provided
b.	Copy of registration letter and last renewal status.	Provided
c.	Document in support of proposed change.	Provided
d.	Analytical reports as per monograph of FPP.	
e.	Undertaking that: i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum/court of law regarding this product. iii. 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. iv. The provided information/ documents are true/ correct.	Provided

Sr. #	Reg. No.	Name of Drug (s) with composition & Existing composition	Date of i. Initial Reg. & ii. Last Renewal Application	Proposed Specification	Remarks
i.	**M/s Mediate Pharmaceuticals (Pvt.) Ltd,Plot#150-151, Sector 24, Korangi Industrial Area, Karachi**				
1.	008952	Diazomil 5mg Tablets Each tablet contains: Diazepam…….....5mg	i. 09-Mar-2004 ii. 18-Jan-2016	BP Specifications	
2.	009354	Phanobarbitone 30mg tablets Each tablet contains: Phanobarbitone ……..30mg		USP Specifications	
3.	032441	Lomitomed tablets Each tablet contains: Diphenoxylate HCl…….2.5mg Atropine sulphate…….....25mcg	i. 25-Aug-2004 ii. 07-Aug-2014	USP Specifications	
ii.	**M/s Genix Pharma (Pvt.) Ltd, 44, 45-K, Korangi Creek Road, Karachi**				
4.	073671	Water for Injection Each ampoule contains: Water for Injection	i. 10-Jan-13 Renewal within due date.	BP Specification	
5.	073468	Dorlol Eye Drop	i. 4-Oct-12	BP	

		Each ml contains: Dorzolmide hydrochloride eq.to Dorzolmide …….....20mg Timolol maleate eq.to timolol.…5mg	Renewal within due date.	Specification	
6.	015143	Efecip 250mg tablets Each tablet contains: Ciprofloxacin HCl ……..250mg	i. 5-Mar-94 Renewal within due date.	USP Specification	
7.	018141	Efecip 500mg tablets Each tablet contains: Ciprofloxacin eq.to Ciprofloxacin HCl Monohydrate…….500mg		USP Specification	
8.	061625	Mep 20mg Capsule Each capsule contains: Omeprazole enteric coated pellets eq. to Omeprazole……..20mg	i. 6-Jul-10 Renewal within due date.	USP Specification	
9.	061626	Mep 40mg Capsule Each capsule contains: Omeprazole enteric coated pellets equivalent to Omeprazole…….40mg		USP Specification	
10.	073680	Plop Forte Ophthalmic solution Each ml contains: Olopatadine hydrochloride eq.to Olopatadine...2mg	i. 10-Jan-13 Renewal within due date.	USP Specification	
11.	042421	S-Flox 250mg tablets Each table contains: Levofloxacin Hemihydrate equivalent to Levofloxacin ……250mg		USP Specification	
12.	042422	S-Flox 500mg tablets Each table contains: Levofloxacin Hemihydrate equivalent to Levofloxacin…….500mg		USP Specification	
13.	073471	X-Gen 0.5% Eye Drops Each ml contains: Moxifloxacin HCl eq.to Moxifloxacin ……5mg	04.Oct.2012 Renewal within due date.	USP Specification	
14.	039087	Zoleric 20mg Capsule Each capsule contains: Esomeprazole Magnesium Trihydrate 22.3mg eq. to Esomeprazole ……..20mg	02.June.2005 Renewal within due date.	USP Specification	
15.	035817	Zoleric 40mg Capsule Each capsule contains: Esomeprazole Magnesium Trihydrate 44.5mg eq.to Esomeprazole.……40mg	31.12.2004 Renewal within due date.	USP Specification	
16.	055679	Depsit 5mg tablet Each film coated tablet contains: Escitalopram (as Oxalate)…….5mg	03.April.14 Renewal within due date.	USP Specification	
17.	055680	Depsit 20mg tablet Each film coated tablet contains: Escitalopram (as Oxalate)…….20mg	03.April.14 Renewal within due date.	USP Specification	
18.	076433	Gvia 50mg tablet Each film coated tablet contains: Sitagliptin Phosphate equivalent to Sitagliptin ..…50mg	22.April.14 Renewal within due date.	USP Specification	
19.	076432	Gvia 100mg tablet Each film coated tablet contains:	22.April.14	USP Specification	

		Sitagliptin Phosphate equivalent to Sitagliptin….100mg	Renewal within due date.		
20.	076435	Respicare 4mg Sachet Each sachet contains: Montelukast sodium equivalent to Montelukast…..4mg	22.April.14 Renewal within due date.	USP Specification	
iii.	**M/s Hilton Pharma (Pvt.) Ltd, Plot# 13 & 14, Sector 15, Korangi Industrial Area, Karachi**				
21.	037707	Citanew 5mg Tablets Each tablet contains: Escitalopram Oxalate as eq.to Escitalopram…….5mg	31.March.2005 Renewal within due date.	USP Specification	
22.	036426	Citanew 10mg Tablets Each tablet contains: Escitalopram (as Oxalate)…….10mg	31.Dec2004 Renewal within due date.	USP Specification	
23.	037681	Citanew 20mg Tablets Each tablet contains: Escitalopram Oxalate as eq.to Escitalopram……20mg	31.March.2005 Renewal within due date.	USP Specification	
24.	006524	Transamin 250mg Capsule Each capsule contains: Tranexamic Acid …….250mg	14.October.1982 Renewal within due date.	JP Specification	
25.	009730	Transamin 500mg Capsule Each capsule contains: Tranexamic Acid …….500mg	21.April.1988 Renewal within due date.	JP Specification	
26.	039695	Myteka Sachet Each sachet contains: Montelukast Sodium eq.to Montelukast…….4mg	02.Dec.2005 Renewal within due date.	USP Specification	
27.	066949	Lerace 500mg Injection Each 5ml ampoule contains: Levetiracetam ……..500mg	i. 29-Oct-2010 ii. 25-May-2015	USP Specification	
iv.	**M/s AGP Limited, B-23-C, S.I.T.E, Karachi**				
28.	024651	Melfax 15mg tablets Each tablet contains: Meloxicam ……15mg	i. 26-Apr-2002 ii. 28-Feb-2017 Transfer of Reg. iii. 31-Mar-2007	USP Specification	
29.	024650	Melfax 7.5mg tablet Each tablet contains: Meloxicam…….7.5mg		USP Specification	
30.	036121	Afoxin 250mg tablet Each tablet contains: Clarithromycin…….250mg	i. 31-Dec-2004 ii. 20-Sep-2017 Change of Br. Name iii. 29-Dec-2009 iv. 7-May-2011	USP Specification	
31.	036122	Afoxin 500mg tablet Each tablet contains: Clarithromycin…….500mg		USP Specification	
32	027659	Gastasid 20mg tablet Each tablet contains: Pantaprazole Sodium Sesquihydrate 22.6mg equ.to Pantaprazole ….20mg	i. 10-May-2002 ii. 6-Apr-2017 Transfer of Reg. iii. 7-May-2007	USP Specification	
33.	027660	Gastasid 40mg tablet Each tablet contains: Pantaprazole Sodium Sesquihydrate 45.1mg equ.to Pantaprazole ….40mg	i. 29-Jun-2002 ii. 6-Apr-2017 Transfer of Reg. iii. 7-May-2007	USP Specification	
34.	055119	Poze G 2/30mg tablet Each tablet contains:	i. 2-Mar-2009 ii. 30-Jan-2019	USP Specification	

		Glimepiride …….2mg Pioglitazone (as HCl)……..30mg			
35.	055120	Poze G 4/30mg tablet Each tablet contains: Glimepiride …….4mg Pioglitazone (as HCl)……..30mg		USP Specification	
36.	055133	Pozemet 15/500mg tablet Each tablet contains: Metformin HCl …….500mg Pioglitazone (as HCl)……15mg	i. 4-Mar-2009 ii. 25-Jan-2019	USP Specification	
37.	050356	Axid Neo 20mg Capsules Each capsule contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate) ……20mg	i. 4-Aug-2008 ii. 25-Jan-2019	USP Specification	
38.	050357	Axid Neo 40mg Capsules Each capsule contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate) ……20mg		USP Specification	
39.	048717	Esi-Dep 10mg tablets Each tablet contains: Escitalopram (as Oxalate)……10mg	i. 16-Jul-2008 ii. 20-Jun-2018	USP Specification	
40.	048718	Esi-Dep 20mg tablets Each tablet contains: Escitalopram (as Oxalate)……20mg		USP Specification	
41.	015673	Algocin 250mg tablet Each tablet contains: Ciprofloxacin HCl eq.to 250mg Ciprofloxacin base	i. 20-Sep-1994 ii. 6-Sep-2012 **Transfer of Reg.** iii. 28-Sep-2007	USP Specification	
42.	015674	Algocin 500mg tablet Each tablet contains: Ciprofloxacin HCl equivalent to 500mg Ciprofloxacin base		USP Specification	
43.	036270	Rubiject Injection Each 5ml contains: Iron Sucrose complex eq.to Elemental Iron …….100mg	i. 13-Jan-2005 ii. 8-Jan-2015	USP Specification	
44.	034708	Lucast 4mg chewable tablet Each tablet contains: Montelukast Sodium 4.160mg eq. to Montelukast …….4mg	i. 3-Dec-2004 ii. 16-Oct-2014	USP Specification	
45.	048716	Lucast 4mg Sachet Each sachet contains: Montelukast (as Sodium)…….4mg	i. 16-Jul-2008 ii. 20-Jun-2018	USP Specification	
v.	**M/s Saydon Pharmaceutical Industries (Pvt.) Ltd, 77/A, Hayatabad Industrial Estate, Peshawar.**				
46.	080233	Sadoquil 100mg tablets Each film coated tablet contains: Quetiapine fumarate =Quetiapine ……100mg (Manufacturer's Specification)	29.Feb.2016	USP Specification	
47.	092452	Sadoquil XR 200mg tablets Each film coated extended release tablet contains: Quetiapine (as fumarate)……..200mg (As per *Innovator's Specifications)	19.Sep.2018	USP Specification	
48.	092453	Sadoquil XR 300mg tablets Each film coated extended release tablet contains:	17.Sep.2018	USP Specification	

		Quetiapine (as fumarate)……..300mg (As per *Innovator's Specifications)			
49.	092454	Sadoquil XR 400mg tablets Each film coated extended release tablet contains: Quetiapine (as fumarate)……..400mg (As per *Innovator's Specifications)	17.Sep.2018	USP Specification	
vi.	**M/s Scilife Pharma (Pvt.) Ltd, Plot No.FD-57/58-A2, Korangi Creek Industrial Park, Karachi.**				
50.	092752	Asthiven 5mg tablet Each chewable tablet contains: Montelukast as Sodium ……5mg (BP Specification)	30.Nov.2018	USP Specification	Asthiven 4mg tablet has already been registered as per USP Specification.
51.	092753	Asthiven 10mg tablet Each film coated tablet contains: Montelukast as Sodium ……10mg (BP Specification)	30.Nov.2018	USP Specification	
vii.	**M/s Atco Laboratories Limited, B-18, SITE, Karachi**				
52.	026225	Lame Tablet Each tablet contains: Lisinopril dihydrate eq.to Lisinopril base…….5mg	i. 14-Dec-2006 ii. 2-Dec-2015	USP Specification	
53.	026226	Lame Tablet Each tablet contains: Lisinopril dihydrate eq.to Lisinopril base…10mg		USP Specification	
54.	016600	Ascard 75mg Tablet Each enteric coated tablet contains: Acetylsalicylic acid ……..75mg	i. 25-Jan-1995 ii. 17-Dec-2014	BP Specification	
55.	022322	Ascard 150mg Tablet Each enteric coated tablet contains: Aspirin Crystalline Powder…..150mg	i. 22-Sep-1998 ii. 13-Aug-2018	BP Specification	
56.	053356	IPNEB Inhalation Solution Each ml contains: Ipratropium Bromide ……0.25mg	i. 15-Dec-2008 ii. 25-Nov-2018	BP Specification	
57.	030905	Merol 25mg Tablet Each tablet contains: Metoprolol Tartarate BP…….25mg	i. 25-Jul-2008 ii. 29-Jul-2018	USP Specification	
58.	024519	Merol 100mg Tablet Each tablet contains: Metoprolol Tartarate ……100mg	i. 12-Mar-2002 ii. 24-Feb-2017	USP Specification	
59.	024514	Prolox Eye Drops Each ml contains: Ciprofloxacin HCl BP eq.to Ciprofloxacin base …….3mg		USP Specification	
60.	058428	Clonexa 1mg Tablet Each film coated tablet contains: Eszopiclone ……1mg	i. 31-Aug-2009 ii. 22-Jul-2014	USP Specification	
61.	058429	Clonexa 2mg Tablet Each film coated tablet contains: Eszopiclone ……2mg		USP Specification	
62.	058430	Clonexa 3mg Tablet Each film coated tablet contains: Eszopiclone ……3mg		USP Specification	
63.	061339	Ivermite 6mg tablet Each film coated tablet contains: Eszopiclone ……6mg	i. 27-Apr-2010 ii. 20-Mar-2015	USP Specification	
64.	030904	Bracin D Sterile Ophthalmic Suspension	i. 25-Jul-2003	USP	

		Each ml contains: Tobramycin BP …….3.00mg Dexamethasone BP ……1.00mg	ii. 29-Jun-2018	Specification	
65.	037465	Hyderquin 2% Cream Each gm contains: Hydroquinone ……..2.00gm	i. 28-Feb-2005 ii. 16-Jan-2015	USP Specification	
66.	026691	Betaxol Eye Drops Each ml contains: Betaxolol HCl BP 5.6mg eq.to Betaxolol base ……5mg	i. 12-Feb-2001 ii. 08-Jan-2016	BP Specification	
67.	053459	Milron Injection Each ml contains: Milrinone (as Lactate) …….1.00mg	i. 19-Jan-09 ii. 14-Dec-14	USP Specification	
68.	053094	Zincat OD Syrup Each 5ml contains: Zinc Sulfate Monohydrate equivalent to Elemental Zinc …….20mg (Oral Electrolyte replacer)	10.Nov.2008 Renewal within due date	USP Specification	
69.	037471	Soneta 2mg Tablets Each tablet contains: Tizanidine HCl 2.288mg equivalent to Tizanidine ……..2mg	28.Feb.2005 Renewal within due date	USP Specification	
70.	037470	Skin-A Cream Each gm contains: Tretinoin ……..0.5mg	i. 28-Feb-2005 ii. 16-Jan-2015	USP Specification	
71.	024516	Clobederm Lotion Each 100ml contains: Clobetasol Propionate …..0.05gm	i. 12-Mar-2002 ii. 22-Feb-2017	USP Specification	
72.	037367	Xylor Syrup Each 5ml contains: Loratadine ……5mg	i. 24-Feb-2005 ii. 16-Jan-2015	USP Specification	
73.	027534	Xylor 10mg tablet Each tablet contains: Loratadine ……..10mg	i. 23-May-2002 ii. 21-Apr-2017	USP Specification	
74.	039193	Hyderquin 4% Cream Each 100gm contains: Hydroquinone ……..4.00gm	i. 24-May-2005 ii. 9-Apr-2015	USP Specification	
75.	024976	Mesulid 100mg tablet Each tablet contains: Nimesulide ……..100mg	i. 3-Jul-1999 ii. 19-Jun-2014	-	
76.	048555	Atcopram 10mg tablet Each film coated tablet contains: Escitalopram (as Oxalate)……..10mg	i. 20-Mar-2008 Renewal confirmed from RRR Section	USP Specification	
77.	058434	A-Fantrine BD Tablet Each tablet contains: Artemether ……..80mg Lumefantrine ……480mg	i. 31-Aug-2009 Renewal confirmed from RRR Section	IP Specification	
78.	073870	A-Fantrine 80mg Injection Each ml contains: Artemether ……80mg	i. 27-Mar-2013 Renewal confirmed from RRR Section	IP Specification	
79.	058354	A-Fantrine Dry Suspension Each ml contains: Artemether ……..15mg Lumefantrine ……90mg	i. 13-Aug-2009 Renewal confirmed from RRR Section	IP Specification	
80.	053368	A-Fantrine DS tablet Each tablet contains: Artemether ……..40mg	i. 16-Dec-2008 Renewal confirmed	IP Specification	

		Lumefantrine …….240mg	from RRR Section		
81.	058431	Atconate 150mg tablet Each film coated tablet contains: Risedronate Sodium……..150mg	i. 31-Aug-2009 Renewal confirmed from RRR Section	USP Specification	
82.	067528	Acsolve 1% Lotion Each ml contains: Clindamycin as Phosphate ….1%w/w	i. 06-Apr-2011 Renewal confirmed from RRR Section	USP Specification	
83.	050526	Adapco Cream Each gm contains: Adapalene ……0.1% w/w	i. 29-Aug-2008 Renewal confirmed from RRR Section	BP Specification	
viii.	**M/s Bosch Pharmaceuticals (Pvt.) Ltd, 221 Bosch House, Sector 23, Korangi Industrial Area, Karachi.**				
84.	047203	Izilon 400mg Tablets Each film coated tablet contains: Moxifloxacin (as HCl) …..400mg (Manufacturer's Specification)	i. 30-Oct-2007. ii. 22-May-2017	USP Specification	
85.	055638	Bvir 0.5mg tablet Each film coated tablet contains: Entecavir USP… …..0.5mg	i. 2-Apr-2009 ii. 28-Nov-2018	USP Specification	
86.	035546	Beasy 10mg tablet Each film coated tablet contains: Montelukast Sodium USP equivalent to Montelukast……..10mg	i. 30-Dec-2004 ii. 3-Apr-2014	USP Specification	
87.	027169	Variba 100mg capsule Each capsule contains: Ribavirin USP ……..100mg	i. 24-Jul-2001 ii. 20-Feb-2016	USP Specification	
88.	027170	Variba 200mg capsule Each capsule contains: Ribavirin USP ……..200mg		USP Specification	
89.	027171	Variba 400mg capsule Each capsule contains: Ribavirin USP ……..400mg		USP Specification	
90.	034879	Orva 10mg tablet Each tablet contains: Atorvastatin (as Calcium trihydrate) ……10mg	i. 9-Nov-2004 ii. 26-Sep-2014 Change of Br. Name iii. 14-Sep-2005	USP Specification	
91.	033961	Orva 20mg tablet Each tablet contains: Atorvastatin (as Calcium trihydrate) ……20mg	i. 21-Sep-2004 ii. 26-Sep-2014 Change of Br. Name iii. 14-Sep-2005	USP Specification	
92.	034880	Orva 40mg tablet Each tablet contains: Atorvastatin (as Calcium trihydrate) ……40mg	i. 9-Dec-2004 ii. 26-Sep-2014 Change of Br. Name iii. 14-Sep-2005	USP Specification	
93.	055017	Zezot 500mg Injection Each vial contains: Azithromycin as dihydrate USP equivalent to Azithromycin ….500mg	i. 9-Dec-2004 ii. 26-Sep-2014	USP Specification	

Decision: Registration Board acceded to request of firms for change in finished product specifications of above mentioned products as per pharmacopeia/ official monographs details recorded above.

Case No.95: Change of Registration Status of M/s Le Mendoza Pharmaceuticals (Pvt.) Ltd, Karachi

The title of the firm has been changed from M/s. Chas .A. Mendoza (DML No. 000140) to M/s Le Mendoza Pharmaceuticals (Pvt.) Ltd., Karachi vide letter No.F.6-1/13-Lic (M-232) dated 2nd September, 2013. The firm applied on 26-4-2014 for transfer of registration of following products due to change in Company Name / Title Name from M/s Chas A. Mendoza Karachi to M/s Le Mendoza Pharmaceutical (Pvt.) Ltd Karachi, where the DML and site remains the same and case was considered in the 277th meeting of Registration Board. The Board decided to send letter to the RRR section for verification of Renewal status. Subsequently, firm has applied vide S.R.O. 1005(I)/2017 and submitted three times renewal fee for each product, whose renewal has been expired in previous years.

Sr. No	Reg. No.	Name of product along with composition	Initial Date of Reg.	Fee along with date	Remarks	Renewal validity till
1.	067028	Essocam 20mg Capsules Each capsule contains:- Esomeprazole enteric coated pellets eq to Esomeprazole .20mg	12/11/2010	(Due date: 11-11-2015) Rs.30,000/- 04-12-2017	Differential fee for renewal submitted.	11-11-2020
2.	067029	Essocam 40mg Capsules Each capsule contains:- Esomeprazole enteric coated pellets eq to Esomeprazole .40mg	12/11/2010	(Due date: 11-11-2015) Rs.30,000/- 04-12-2017	Differential fee for renewal submitted.	11-11-2020

The Registration Board in its 277th meeting deferred the above products for submission of legalized source of Esomeprazole respectively and differential fee. Now, the firm has requested that they have already approved source of pellets for above products i.e. "M/s. Goldfish Pharma Pvt. Ltd. # 5-5/328, Opp. NCS Complex Prashanth Nagar, Hyderabad, India and the same is mentioned in registration letter. They have further stated that they had deposited three time fee for renewal of the above products and requested to change the registration status of above products from previous name to new name of the firm.

Decision of the 284th meeting:-

Registration Board approved change in registration status of above products from M/s. Chas .A. Mendoza, Karachi (DML No. 000140) to M/s. Le Mendoza Pharmaceuticals (Pvt.) Ltd., Karachi (DML No. 000140). However, the Board authorized chairman to issue approval letter after submission of legalized GMP certificate for the source of pellets i.e. "M/s. Goldfish Pharma Pvt. Ltd. # 5-5/328, Opp. NCS Complex Prashanth Nagar, Hyderabad, India.

Request of the firm:-

Now the firm has requested that approval letter for change of title from M/s. Chas .A. Mendoza (DML No. 000140) to M/s Le Mendoza Pharmaceuticals (Pvt.) Ltd., Karachi may be issued in respect of above stated drugs with new source of Pellets (M/s Vision Pharmaceutical (Pvt.) Ltd, Islamabad) as they have already furnished all required documents of new source i.e. M/s Vision Pharmaceutical (Pvt.) Ltd, Islamabad.

The firm has submitted the following documents;

i. Fees of Rs. 20,000/- for each product.
ii. Stability data.
iii. cGMP of M/s Vision Pharmaceuticals, Islamabad (26-January-2018)

Decision: Registration Board acceded to request of firm for change in title of manufacturer from M/s. Chas .A. Mendoza, Karachi to M/s. Le Mendoza Pharmaceuticals (Pvt.) Ltd., Karachi and approved source of pellets i.e M/s Vision Pharmaceutical (Pvt.) Ltd, Islamabad

Case No. 96: Request For Change in Registration Status of Products From M/s. High-Q International, Karachi To M/s. High-Q Pharmaceuticals, Karachi.

M/s. High-Q International, D-106, KDA-1, Karsaz Road, Karachi has requested (under sub rule 1a of rule 20-A) for change of registration status of following products from import to local on contract manufacturing at M/s. High-Q Pharmaceuticals, Plot No.224, Sector 23, Karachi). The details are given as under:

S.No.	Reg. No.	Name of Drug and Composition	Approved Pack/MRP	Registration History	Dy.No, Date & Fees/Remarks
1.	014945	Famopsin-20 Tablets Each film coated tablet contains: Famotidine.....20mg	20's/ As per S.R.O 471/(I)/93	Initial Reg. Letter 19-05-1994	Dy.No.441/DDC (Reg-I) 10-05-2019 **Duplicated Dossiers** 30-09-2016 Yellow copy of challan of Rs.50,000/-
2.	014946	Famopsin-40 Tablets Each film coated tablet contains: Famotidine.....40mg	10's/ As per S.R.O 471/(I)/93	Initial Reg. Letter 19-05-1994	Dy.No.441/DDC(Reg-I) 10-05-2019 **Duplicated Dossiers** 30-09-2016 Yellow copy of challan of Rs.50,000/-
3.	019524	Remethan 100R Tablets Each film coated tablet contains: Diclofenac Sodium.....100mg	30's/ As per S.R.O 471/(I)/93	Initial Reg. Letter 17-11-1996	Dy.No.441/DDC(Reg-I) 10-05-2019 **Duplicated Dossiers** 30-09-2016 Yellow copy of challan of Rs.50,000/-
4.	018943	Remethan 50 Enteric Coated Tablets Each tablet contains: Diclofenac Sodium.....50mg	20's/ As per S.R.O 471/(I)/93	Initial Reg. Letter 17-04-1996	Dy.No.441/DDC(Reg-I) 10-05-2019 **Duplicated Dossiers** 30-09-2016 Yellow copy of challan of Rs.50,000/-

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. Copy of DML with detail of approved sections as below,
   - Tablet (General)
   - Tablet (General Antibiotic/Quinolone)
   - Tablet (Psychotropic)
   - Liquid (General)
   - Capsule (General)
iv. Copy of last GMP inspection of M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi, dated 12-09-2018, indicating "Good" level of GMP compliance.
v. Contract agreement between M/s High-Q International, Karachi and M/s High-Q Pharmaceuticals, Karachi, dated 16-03-2019.
vi. NOC from M/s High-Q International, Karachi dated 07-05-2019
vii. NOC for contract manufacturing from M/s High-Q Pahrmaceuticals, Karachi dated 07-05-2019

viii. Copy of Renewal of DML (M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi) as per Licensing Division Letter No.F.2-2/2004-Lic (Vol-II) dated 27th January, 2017.

ix. Copy of Renewal of DSL valid from 22-Jun-2017 to 21-Jun-2019.

Decision: **Registration Board was apprised that M/s High-Q International, Karachi has provided NOC from manufacturer i.e M/s Remedica Ltd. Aharnon street, Cyprus hence Registration Board acceded to request of firm for local manufacturing of above mentioned imported products of M/s High-Q International, Karachi on contract manufacturing basis by M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi.**

Case No.97: Change in Name of Manufacturer Abroad.

M/s Bayer Pakistan (Pvt) Limited, Karachi has requested for change in the name of their principal manufacturer for following products registered for bulk import and local repackaging:

S.No	Reg. No	Name of Drug(s) & Composition	Current Name of Manufacturing Site	Proposed Name of Manufacturing	Documents Submitted
1	010453	Ciproxin infusion 0.1g Each 50ml contain ciprofloxacin….0.1g.	Manufactured By: Bayer Schering, Pharma AG Leverkusen, Germany Packed By: Bayer Pakistan (Pvt) Limited, C-21. S.I.T.E, Karachi Product License Holder: Bayer Vital GmbH, 51368, Leverkusen, Germany Packed By: Bayer Pakistan (Pvt) Limited, C-21. S.I.T.E, Karachi	Manufactured by: Bayer AG, Kaiser-Wilhelm-Allee 51368, Leverkusen, Germany Product License Holder: No Change Packed By: No Change	Original Legalized CoPP from Germany.
2	014935	Ciproxin infusion 0.2g Each 100ml contain ciprofloxacin….200mg.	Manufactured By: Bayer Pharma AG, Leverkusen, 51368, Germany Product License Holder: Bayer Vital GmbH, 51368, Leverkusen, Germany Packed By: Bayer Pakistan (Pvt) Limited, C-21. S.I.T.E, Karachi	Manufactured by: Bayer AG, Kaiser-Wilhelm-Allee 51368, Leverkusen, Germany. Product License Holder: No Change Packed By: No Change	Original Legalized CoPP from Germany. Original Legalized CoPP from UK.
4	010454	Nimotop Tablets Each vial contains:- Nimodipine …..0.01g	Manufactured By: Bayer Pharma AG, Leverkusen, 51368, Germany Product License Holder: Bayer Vital GmbH, 51368, Leverkusen, Germany Packed By: Bayer Pakistan (Pvt) Ltd, C-21.	Manufactured by: Bayer AG, Kaiser-Wilhelm-Allee 51368, Leverkusen, Germany. Product License Holder: No Change Packed By:	Original Legalized CoPP from Germany

			S.I.T.E, Karachi	No Change	

The firm has submitted following documents:

1. Fee of Rs. 5,000/- for each product.
2. Copy of initial registration letter and renewal submissions.

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Decision: Registration Board acceded to firm's request for change in title of manufacturer of above mentioned products from Bayer Pharma AG, Leverkusen, 51368, Germany to Bayer AG, Kaiser-Wilhelm-Allee 51368, Leverkusen, Germany (manufacturing site remains same)

Case No. 98: Standard Operating Procedures for Approval of Post-Registration Variations.

Registration Board in 283rd meeting considered and approved revised SOPs for processing of post registration variations. In SOP's of following post registration variations "Form-5/ Form5-A" is required:

Sr. No	Post Registration Variation wherein Form5/Form 5A is required	Description
1.	Registration of Product from One Manufacturer to another Manufacturer with Change in Manufacturing Site.	For locally manufactured products
2.	Registration of Product after Change in Name / Title of Manufacturer (Site of Manufacturing Remains the Same)	
3.	Change of Address of Manufacturing Site/Source/Marketing Authorization Holder (MAH).	For imported products
4.	Change in Shelf Life.	
5.	Registration of Product from One importer to another Importer	

Since applications on CTD format have been implemented from now and onward hence opinion is being solicited from Registration Board whether application on CTD shall be required for processing such cases or any further direction as the Board may deem appropriate.

Decision: The case was deferred for futher deliberation.

Case No.99. Applications referred by 27TH PRVC for export registration

Following applications were considered in 27th PRVC (held on 25-04-2019) and referred to Registration
Board, as per details below

1) Registration of Drug(s) of M/s Wilshire Pvt Ltd Lahore for Export purpose.

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	**Suvia Sublingual tablet** Each Sublingual tablet contains: Sufentanil as Citrate.....0.03mg	**USFDA Approved.**	Dy No.388/2019- PE&R-EFD-DRAP dated 7.03.2019.

Requirements As Per SOP	Submitted Documents [Ref.F.No.27-PRVC/2019-(EFD)-DRAP]
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5-D; Rs.50,000/-Each dated 05.03.19.
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML dated 21-07-2015 Approval of relevant section verified from Lic. section letter No.F.1-65/84-Lic (Vol-II) (M-222)(P: 418/C)
GMP Status. Copy of Inspection report/GMP certificate.	GMP Status "**Satisfactory**" Verified from inspection report dated 27-08; 05.10 & 06.11.18.
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Decision: Registration Board approved above mentioned product of M/s Wilshire Labs Pvt Ltd Lahore for export registration.

2) Registration of Drug(s) of M/s Mafins Pharma, A-5, S.I.T.E Super Highway Industrial Area, Karachi.

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date &Remarks.
I	II	III	IV
1.	**Arinaf Forte tablet** Each tablet contains: Ibuprofen.....400mg Pseudoephedrine HCl.....60mg	**Dolocol Forte** Tablet by Semos Pharma. **(Reg.#. 028204)**	Dy. No.433 /2019-PE&R-(EFD) 20.03.2019 Rs.20,000/- dated 15.03.2019.
2.	**Panamol CF tablet** Each film coated tablet contains: Paracetamol.....500mg Chlorpheniramine (as Maleate)...4mg Pseudoephedrine HCl.....60mg	**Panadol CF** tablet by GSK Pharma. **(Reg.#. 013113)**	Dy. No.432 /2019-PE&R-(EFD) 20.03.2019 Rs.20,000/- dated 15.03.2019.

Requirements As Per SOP	Submitted Documents [Ref.F.No.27-PRVC/2019-(EFD)-DRAP].
Application on Form 5/Form 5-D with required fee as per relevant SRO.	Applications on Form5; Rs.20, 000/- for each product dated 15.03.19

Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML dated 22-06-2015 (Page.1224/C). Approval of relevant section verified from Lic. Section letter No. F2-10/2009-Lic dated 26.06.15
GMP Status.(Copy of Inspection report/GMP certificate)	GMP inspection report conducted on 05.10.17 **Concluded as Good level**
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided.

Decision: Registration Board approved above mentioned products of M/s Mafins Pharma, A-5, S.I.T.E Super Highway Industrial Area, Karachi for export registration.

Case No.100: Export Registration of Linagliptin,

Following applications of Linagliptin were considered by Registration Board and deferred due to IPO issue.

S.No	Name of firm	Product name and composition	Application details	Remarks
1.	M/s. Schazoo Pharmacetuical Laboratories (Pvt) Ltd; Sheikhupura	Lina-K 5mg Tablet Each Tablet contains:- Linagliptin…….5mg	Fee of Rs. 50000 for this purpose Form-5D. Dated 02.06.2017	deferred in 271st meeting for comments of IPO
2.	M/s. High-Q Pharmaceuticals, Karachi	Empaglin Tablet Each film coated tablet contains: Empagliflozin……10mg Linagliptin……..5mg	Fee of Rs. 50000 for this purpose Form Dated 20.09.2017	Considered in 278th meeting. Deputy Director, Legal Affair Division, DRAP was advised to follow up the matter with IPO Pakistan for their response.
3.	**do**	Empaglin Tablet Each film coated tablet contains: Empagliflozin……25mg Linagliptin……..5mg	Fee of Rs. 50000 for this purpose Form Dated 20.09.2017	
4.	**do**	Letrum-M Tablet Each film coated tablet contains: Linagliptin……..…2.5mg Metformin HCl……..500mg	Fee of Rs. 50000 for this purpose Form Dated 20.09.2017 14.12.2017	
5.	**do**	Letrum-M Tablet Each film coated tablet contains: Linagliptin……2.5mg Metformin HCl……..850mg	Fee of Rs. 50000 for this purpose Form Dated 20.09.2017 14.12.2017	
6.	**do**	Letrum-M Tablet Each film coated tablet contains: Linagliptin……2.5mg Metformin HCl ……..1000mg	Fee of Rs. 50000 for this purpose Form Dated 20.09.2017 14.12.2017	
7.	**do**	Letrum Tablet Each film coated tablet contains: Linagliptin……5mg	Fee of Rs. 50000 for this purpose Form Dated 20.09.2017	

			14.12.2017	
8.	M/s. Getz Pharma Pvt Ltd. Karachi	Linapta Tablets 5mg Each film coated tablet contains: Linagliptin ……5mg	Dy No.38-PE&R-(EFD) 23.10.2018 Rs.50,000/-	
9.	M/s Searle Company Limited, Karachi	DIALIN 5MG TABLET Each film coated tablet contains: Linagliptin…….5mg	Dy No.43-PE&R-(EFD) 29.10.2018 Rs.50,000/-	Considered in 286th meeting Registration Board deferred the case for further deliberation in the light of views/comments furnished by IPO Pakistan.
10.	**do**	DIALIN-M 2.5MG+850MG TABLET Each film coated tablet contains: Linagliptin…….2.5mg Metformin HCI…….850mg	Dy No.44-PE&R-(EFD) 29.10.2018 Rs.50,000/-	
11.	**do**	DIALIN-M 2.5MG+1000MG TABLET Each film coated tablet contains: Linagliptin…….2.5mg Metformin HCI….1000mg	Dy No.46-PE&R-(EFD) 29.10.2018 Rs.50,000/-	
12.	**do**	DIALIN M 2.5MG+500MG TABLET Each film coated tablet contains: Linagliptin…….2.5mg Metformin HCI…….500mg	Dy No.45-PE&R-(EFD) 29.10.2018 Rs.50,000/-	
13.	M /s. CCL Pharmaceuticals (Pvt) Ltd, Lahore	Ccldiolin tablet 5mg Each film coated tablet contains:- Linagliptin……..5mg	Dated 21.03.2018 **Rs 20,000**/-	Considered in 287th meeting Deferred product for further deliberation.

Decision: **The case was discussed on 2nd day of the meeting and Registration Board approved above mentioned formulations of firms for export registration, in the light of decision of Registration Board in 288th meeting except product of M/s CCl pharmaceuticals, Lahore at Sr. No. 13 for differential fee of Rs 30,000/-. Later on (3rd day), Mr.Ghulam Mujtaba, representative of IPO shared following note of dissent:**

"The Linagliptin is a patented drug and at present, its patent(s) is/are valid and enforced in Pakistan under section 30 and 31 of the Patents Ordinance, 2000. All the commercialization rights including exporting of a patented product is only confreres to patentee under the law. The Honorable Sindh High Court has also confirmed these rights specifically in this particular case of enforcement of patent of Linagliptin. Despite, the clear legal binding confirmed by the High Court, the registration of Linagliptin to third parties were approved by the Chairman Drug Registration Board in 27th Post Registration Variation Committee (PRVC) meeting held on 25/04/2019 and the Registration Board in 289th meeting of the Board.
IPO Pakistan completely disagree with the decision of registration of Linagliptin for export purpose listed as Case No.02 and Case No.03 (page no. 1746 to 1748) of the Agenda of 289th meeting of the Drug Registration Board and PRVC. The enforcement of patent right is a binding on Pakistan in lieu of international agreement to which Pakistan is signatory including Paris convention and WTO's TRIPS agreement. The violation of international obligation will create a huge problem for the trade of this country and may invite trade barriers. Therefore, matter may be taken seriously and with due care. The registration of a valid patented drug i.e. Linagliptin by the Board to unauthorized parties is clear violation

of section 30 of the Patents Ordinance 2000 and the Sindh High Court's decision in matter of Patent No. 141311, 141044 and 141068."

Registration Board decided to forward complete case to Legal Affair Division to seek the opinion for consideration of Registration Board.

Case No.101: Information regarding Registration of Linagliptin for export purpose.

Following applications were considered by chairman Registration Board in 27th Post Registration Variation committee (PRVC), held on 25-04-2019 and approved for registration in the light of discussion and deliberation of Registration Board in 288th meeting. Accordingly registration has been granted for export purpose:

S.No	Name of firm	Product name and composition	Application details	Remarks
1.	M/s Medisure Laboratories Pakistan (Pvt) Ltd, Karachi	**Medjenta tablet** Each film coated tablet contains: Linagliptin.....5mg	Dy. No.461 /2019-PE&R-(EFD) 22.03.2019. Form 5-D with	**Approved**
2.	M/s Genix Pharma Pvt Ltd. 44, 45-B, Korangi Creek Road, karachi	**Empalin Tablets** Each film coated tablet contains: Empagliflozin.....25mg Linagliptin.....5mg	Dy. No.503 /2019-PE&R-(EFD) 16.04.2019; Form5D; Rs.50, 000/- dated 08.04.2019	**Approved**
3.	M/s Genix Pharma Pvt Ltd. 44, 45-B, Korangi Creek Road, karachi	**Empalin Tablets** Each film coated tablet contains: Empagliflozin.....10mg Linagliptin.....5mg	Dy. No.504 /2019-PE&R-(EFD) 16.04.2019; Form5D; Rs.50, 000/- dated 08.04.2019	**Approved**

Decision: Registration Board noted the information. However, keeping in view opion of Mr.Ghulam Mujtaba, representative of IPO in above case, the Board decided to forward complete case to Legal Affair Division to seek the opinion for consideration of Registration Board

Case No. 102: Deferred case of 17th PRVC and 24th PRVC.

Registration of Drugs of M/s. Martin Dow Marker Ltd. (Formerly Merck Pvt Ltd) 7, Jail Road, Quetta, Pakistan for Export purpose.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. Fee with date	Remarks
I	**II**	**III**	**IV**	**V**
1.	**Wintogeno Cream** Each gram contains: Methyl Salicylate…12.5% w/w Menthol ……2.5%	Iodex By M/s GSK Pain Gay by M/s Marvi Pharmaceuticals	Dy No.79-PE&R-(EFD) 07.11.2018 Rs.20,000/-	Provided Generic status could not be verified. Iodex By M/s GSK: Iodine 4% + Methyl Salicylate 5% Pain Gay by M/s Marvi (Menthol 10% + Methyl salicylate 15%)

				Wintogeno Balm by M/s Martin Dow: Eucalypto 0.11% + Menthol 2.6% + Methyl Salicylate 12.17% + Thymol 0.11%

Decision of 17th PRVC: - The Committee evaluated and recommended the case in the light of SOPs approved by the Registration Board. Request of firm for registration of above mentioned product at sr. no. 01 for export purpose has been deferred by the Chairman Registration Board for following reason:

i *Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. In case of new molecule, submission of application on form 5D along with differential fee of Rs.30,000/-*

ii *Requisite documents including evidence of approved section, status of DML & undertakings in the light of SOPs approved for export registrations vide 283rd meeting of Drugs Registration Board.*

Later on firm provided evidence of approval in importing country i.e Sri Lanka and submitted following documents:

Sr.#	**Requirements As Per SOP**	**Submitted documents (Ref. File.No.1-3/2019-Pt-I-EFD-DRAP)**
1.	Application with requisite fee.	Form 5-D alongwith PKR 30,000/- fee.
2.	Copy of GMP inspection	GMP inspection report dated 29-01-18.
3.	Copy of DML & Approval of section by CLB.	Copy of DML dated 02-12-2014 Approval of relevant section verified from letter of licensing division No. F.2-6/86-Lic. (Vol-V)
4.	Undertaking for export only purpose.	Provided
5.	Registration status in RRAs or importing country.	Firm submitted copy of registration approval in the importing country i.e., Sri Lanka.

The case was reconsidered in 24th PRVC and decided as follows:

Decision: - The Committee evaluated and recommended the case in the light of SOPs approved by the Registration Board. Chairman Registration Board has referred the request of firm to the Registration Board.

Decision: Since applied formulation is approved in importing country i.e Sri Lanka hence Registration Board approved above mentioned product of M/s. Martin Dow Marker Ltd for export registration.

Case No.103: Change of Brand Name for the product of M/s. CCL Pharmaceuticals (Private) Limited, Lahore.

M/s. CCL Pharmaceuticals (Private) Limited, Lahore has requested for change of brand name of following products as per details below:-

S. No.	Reg. No.	Existing Brand Name	Proposed Brand Name	Justification/ Reasons	Decision in 278th Meeting of Registration Board
1.	025410	Once A Day Tablet Each Tablet contains:- Vitamin A (as acetate and betacarotene)……10mg Vitamin B1 ……...1.5mg Niacin.....20mg Vitamin E …….....30mg Folic Acid…….0.4mg Biotin…….....30mcg Iron.....18mg Phosphorus ……....100mg Magnesium ……100mg Zinc ……..15mg Selenium ……..10mcg Manganese……...2.5mg Chloride ……34mg Vitamin C …….60mg Vitamin B2 ……1.7mg Vitamin D…….10mcg Vitamin B6.....2mg Vitamin B12.....6mcg Pantothenic acid ……..…10mg Calcium ……..130mg Iodine ……..…..150mcg Copper ……2mg Chromium ……10mcg Molybdenum ……10mcg Potassium ……....37.5mg	Once A Day Maximum Tablet	As per marketing requirement.	*Since the proposed brand name contains adjective property hence Registration Board deferred the request of M/s. CCL Pharmaceuticals (Private) Limited, Lahore and advised firm to propose alternate brand name.*

Following documents have been submitted by the firm as per SOP approved by the Registration Board in its 283rd meeting for the purpose of change of brand name for above product:

S. No.	Required documents
a	Application with required fee as per relevant SRO (in case of similarity / resemblance with already registered drug, fee will not be required)
b	Copy of registration letters and renewal status.
d	Justification for proposed change
e	Information regarding previous change of brand name since registration of drugs.
f	Details (batch number, date of manufacture, quantity and stock position) regarding last batch manufactured.
g	i. An undertaking that the proposed names do not resemble with already registered brands. In case of resemblance/similarity with already registered drugs, the applicant will be liable to change immediately. Moreover, no case is pending at any forum / court of law regarding this matter. ii. Undertaking that the provided information/ documents are true/ correct.

Now the firm has proposed following name for the instant product
"Oadmax Tablet"

Decision: Registration Board approved the change in brand name of above product from Once A Day to "Oadmax".

Case No.104: Miscellaneous Case of 27th PRVC

i) M/s. Novamed Pharmaceuticals (Pvt.) Limited, Lahore

Dy. No. 10194 R&I dated 04-03-2019

M/s. Novamed Pharmaceuticals (Pvt.) Limited, Lahore has 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	Remarks
1	059690	Enta-B tablets 0.5mg Each tablet contains:- Entecavir……0.5mg (Novamed's Specs.)	Enta-B tablets 0.5mg Each tablet contains:- Entecavir……0.5mg **(USP Specs.)**	Approved as **film coated tablets** in USFDA and MHRA.
2	043481	Lipilow tablet 10mg Each tablet contains:- Atorvastatin (as calcium trihydrate)…….10mg	Lipilow tablet 10mg Each tablet contains:- Atorvastatin (as calcium trihydrate)……..10mg **(USP Specs.)**	Approved as **film coated tablets** in USFDA and MHRA.
3	043484	Lipilow tablet 20mg Each tablet contains:- Atorvastatin (as calcium trihydrate)…….20mg	Lipilow tablet 20mg Each tablet contains:- Atorvastatin (as calcium trihydrate)……20mg **(USP Specs.)**	Approved as **film coated tablets** in USFDA and MHRA.
4	043496	Lipilow tablet 40mg Each tablet contains:- Atorvastatin (as calcium trihydrate)…….40mg	Lipilow tablet 40mg Each tablet contains:- Atorvastatin (as calcium trihydrate)…….40mg **(USP Specs.)**	Approved as **film coated tablets** in USFDA and MHRA.

Documents details as per SOPs approved 283rd Registration Board Meeting:-

Sr. No.	Documents submitted by the Firm.
1.	Application with required fee as per relevant SRO. If error is on part of firm.
2.	Copy of registration letter and renewal status.
3.	Documents in support of proposed correction
4.	Analytical reports as per monograph of FPP
5.	Undertaking that : The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. No case is pending at any forum / court of law regarding this product. 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. The provided information/ documents are true/ correct.

Decision of 27th PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board.

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.

ii) M/s. Fynk Pharmaceuticals, Lahore.

M/s. Fynk Pharmaceuticals, Lahore has requested for change in specification of following product as per details below:-

Sr. #	Reg No.	Existing Brand Name	Proposed Correction in Formulations	Decision in 27th PRVC:-	Remarks
1.	065884	Egix Syrup Each 5ml contains:- Cetirizine dihydrochloride…….5mg (Fynk's Specification)	Egix Syrup Each 5ml contains:- Cetirizine dihydrochloride……. 5mg **(USP Specification)**	The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board.	Cetirizine 1mg/ml Oral Solution **(MHRA approved)**
2.	049024	Egix Tablet Each tablet contains:- Cetirizine dihydrochloride……..10mg (Fynk's Specification)	Egix Tablet Each film coated tablet contains:- Cetirizine dihydrochloride….10 mg **(USP Specification)**		**(MHRA approved)**

Documents details as per SOPs:

Sr. No.	Documents submitted by firm
1.	Application with required fee as per relevant SRO, if error is on part of firm
2.	Copy of registration letter and last renewal status.
3.	Documents in support of proposed correction
4.	Analytical reports as per monograph of FPP
5.	Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product. iii. 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. iv. The provided information/ documents are true/ correct.

Decision: Registration Board approved the approved finished product specifications of above products i.e. USP Specifications.

iii) M/s. Saffron Pharmaceuticals Pvt. Limited, Lahore

Dy. No. 42144 R& dated 07-12-2019

M/s. Saffron Pharmaceuticals Pvt. Limited, Lahore has 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	Remarks
1	046446	Terbisil tablets Each tablet contains:- Terbinafine USP……..125mg (Saffron's Specifications)	Terbisil tablets Each tablet contains:- Terbinafine **(as HCl)** …….125mg **(USP Specifications)**	MHRA approved
2	052958	Terbisil tablets Each tablet contains:- Terbinafine (as HCl)……..250mg (Saffron's Specifications)	Terbisil tablets Each tablet contains:- Terbinafine (as HCl) ……..250mg **(USP Specifications)**	MHRA approved

Documents details as per SOPs approved 283rd Registration Board Meeting:-

Sr. No.	Documents submitted by the Firm.
1.	Application with required fee as per relevant SRO. If error is on part of firm.
2.	Copy of registration letter and renewal status.
3.	Documents in support of proposed correction
4.	Analytical reports as per monograph of FPP
5.	Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product. iii. 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. iv. The provided information/ documents are true/ correct.

Decision of 27th PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board

Decision: Registration Board approved the correction in following formulation of above product and approved finished product specifications of above products i.e. USP Specifications.

iv) M/s. Akson Pharmaceuticals Pvt. Limited, Mirpur

Dy. No. 8032 R&I dated 22-02-2019

M/s. Akson Pharmaceuticals Pvt. Limited, Mirpur have requested (page 360/C) for change in specifications of their following registered product with details below:-

S. No.	Reg. No.	Name of drug(s) with formulation	Desired specifications	Justification
1	068263	Akzith Capsules Each capsule contains:- Azithromycin……..250mg (BP Specifications)	Akzith Capsules Each capsule contains:- Azithromycin……..250mg **(USP Specifications)**	USP grade API is easily available.

Documents details as per SOPs approved 283rd Registration Board Meeting:-

Sr. No.	Documents submitted by the Firm.
1	Application with required fee as per relevant SRO. If error is on part of firm.
2	Copy of registration letter and renewal status.
3	Documents in support of proposed correction
4	Analytical reports as per monograph of FPP
5	Undertaking that :

	The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. No case is pending at any forum / court of law regarding this product. 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. The provided information/ documents are true/ correct.

Decision of 27th PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board

Decision: Registration Board approved the approved finished product specifications of above products i.e. USP Specifications.

v) M/s. Vega Pharmaceuticals

M/s. Vega Pharmaceuticals (Pvt.) Limited, Lahore has requested for correction of composition and change in specification in Registration letter for following products.

S. No	Reg. No.	Existing Name of Drug(s) & Composition	Desired corrections	RRA availability
I	II	III	IV	VI
	050249	Tilast tablets 120mg Each tablet contains:- Fexofenadine HCl……120mg (Vega's Specs.)	Tilast tablets 120mg Each film coated tablet contains:- Fexofenadine HCl ……120mg (BP Specs.)	MHRA approved
2	050251	Tilast tablets 180mg Each tablet contains:- Fexofenadine HCl……180mg (Vega's Specs.)	Tilast tablets 180mg Each film coated tablet contains:- Fexofenadine HCl……180mg (BP Specs.)	MHRA approved
3	033877	Quinocip eye drops Each ml contains:- Ciprofloxacin (as base)……3mg	Quinocip eye drops Each ml contains:- Ciprofloxacin hydrochloride eq. to Ciprofloxacin……3mg (USP Specifications)	USFDA approved
4	033529	Difsom tablets 50mg Each tablet contains:- Diclofenac Sodium……50mg	Difsom tablets 50mg Each enteric coated tablet contains Diclofenac Sodium……..50mg (BP Specifications)	MHRA approved
5	033535	Tilast tablets 60mg Each tablet contains:- Fexofenadine HCl……60mg (Vega's Specs.)	Tilast tablets 60mg Each film coated tablet contains:- Fexofenadine HCl……60mg (BP Specs.)	USFDA approved

Documents details as per SOPs:

Sr. No.	Documents submitted by firm
1	Application with required fee as per relevant SRO, if error is on part of firm
2	Copy of registratio3 letter and last renewal status.
3	Documents in support of proposed correction
4	Analytical reports as per monograph of FPP
	Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product.

	iii. 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. iv. The provided information/ documents are true/ correct**.**

Decision of 27th PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board.

Decision: Registration Board decided as follow:-

i. Approved the correction in dosage form of above products as mentioned in column IV

ii. Approved finished product specifications of above products i.e. BP Specifications at Sr. No. 1-2 & 4-5

iii. Approved finished product specifications of above products i.e. USP Specifications at Sr. No. 3

vi) M/s. Saffron Pharmaceuticals (Pvt.) Limited, Faisalabad

Dy. No. 13220 R&I dated 06-03-2019

M/s. Saffron Pharmaceuticals (Pvt.) Limited, Lahore has requested for correction of composition in Registration letter for following products.

S. No	Reg. No.	Existing Name of Drug(s) & Composition	Desired corrections	Remarks
I	II	III	IV	V
1.	060344	Valpro 250mg tablet Each tablet contains:- Divalproex as sodium …….250mg (USP Specifications)	Valpro 250mg tablet Each **enteric coated** tablet contains:- Divalproex **Sodium eq. to valproic Acid**…….250mg (USP Specifications)	**USFDA approved**

Documents details as per SOPs:-

Sr. No.	Documents submitted by firm
1	Application with required fee as per relevant SRO, if error is on part of firm. Fee Rs. 5000/- deposited 19-12-2018 and Rs. 15000/- dated 06-03-2019
2	Copy of registration letter and last renewal status.
3	Document in support of proposed correction.
4	Undertaking:- Undertaking that the provided information/ documents are true/ correct.

Decision:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board.

Decision: Registration Board deferred for further deliberation

vii) M/s. Star Laboratories (Pvt.) Limited, Lahore

Dy. No. 17599 R&I dated 10-10-2017

M/s. Star Laboratories (Pvt.) Limited, Lahore has requested for correction of composition in Registration letter for following products.

S. No	Reg. No.	Existing Name of Drug(s) & Composition	Desired corrections	Remarks
I	II	III	IV	V
1	026864	Rocetrax -25 injection IV/IM Each 10ml vial contains:- Ceftriaxone Sodium ……250mg Each 2ml ampoule contains:- Lignocaine HCl……10mg	Rocetrax -25 injection **IM** Each **vial** contains:- Ceftriaxone as Sodium ……250mg **[No solvent as part of registration]**	The firm has given consent about the intended route of administration i.e. IM **USFDA approved**
2	026865	Rocetrax -50 injection IV/IM Each 10ml vial contains:- Ceftriaxone Sodium ……500mg Each 2ml ampoule contains:- Lignocaine HCl……10mg	Rocetrax -50 injection **IM** Each **vial** contains:- Ceftriaxone as Sodium ……500mg **[No solvent as part of registration]**	The firm has given consent about the intended route of administration i.e. IM **USFDA approved**

Documents details as per SOPs:-

Sr. No.	Documents submitted by firm
1	Application with required fee as per relevant SRO, if error is on part of firm. Fee Rs. 5000/- deposited dated 10-10-2017 for each product.
2	Copy of registration letter and last renewal status.
3	Document in support of proposed correction.
4	Undertaking:- Undertaking that the provided information/ documents are true/ correct.

Decision of 27th PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer case to Registration Board.

Decision: Registration Board approved correction in dosage form of above products as mentioned in column-IV. Moreover, the firm will provide diluent for injection for IM route.

Case No.105: Change of source of pellets of M/s. Himont Pharmaceuticals (Pvt.) Limited, Lahore

Dy. No. 9684 R&I dated 01-03-2019

M/s. Himont Pharmaceuticals (Pvt.) Limited, Lahore has applied for change in source of pellets for their following registered product:

Sr. No.	Reg. No.	Name of Product	Existing Source of Pellets	New proposed Source of Pellets	Remarks
1	069066	Klofix-es capsule 20mg Each capsule contains:- Esomeprazole as Megnesium Trihydrate (Pellets)…….20mg (Himont Specifications)	M/s. Smilax Laboratories Ltd. Plot No. 12/A Phas-III IDA, Jeedimetla, Medchal District-500 055, Telangana, India	M/s. Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.	**Official monograph of the applied formulation exists in USP, FPP specifications may be corrected accordingly,**

			Contract manufactured by M/s. Ocean Pharmacoat Pvt. Ltd, Plot No. 44, CIE, Gandhi Nagar, Balangar, Medchal-Malkajgiri District-500 037, Telangana, India		

The details of requirements as per SOPs and the documents submitted by the firm are as under:

Sr. No.	Documents submitted by the Firm.
1.	Application with required Fee Rs.20,000/- dated 27-02-2019
2.	Copy of registration letter and renewal status
3.	Real time stability studies of pellets conducted by manufactured as per condition of zone IV-A as per ICH guideline (Both real time + accelerated)
4.	Certificate of analysis of manufacturer
5.	GMP certificate from regulatory authority of exporting country.
6	Undertaking that a. Shelf life of finished product would be assigned after conducting product development studies, real time and accelerated stability studies on 3 batches of commercial scale, validation of manufacturing process and method of analysis before sale of drug. b. 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. c. That the provided information is true & correct.

Decision: **Registration Board approved the request of M/s. Himont Pharmaceuticals (Pvt.) Limited, Lahore for change in source of pellets of above product from M/s. Smilax Laboratories Ltd. Plot No. 12/A Phas-III IDA, Jeedimetla, Medchal District-500 055, Telangana, India Contract manufactured by M/s. Ocean Pharmacoat Pvt. Ltd, Plot No. 44, CIE, Gandhi Nagar, Balangar, Medchal-Malkajgiri District- 500 037, Telangana, India to M/s. Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad**

Case No.106: M/s. Shrooq Pharmaceuticals, Lahore

M/s. Shrooq Pharmaceuticals (Pvt.) Limited, Lahore has requested for correction of composition and change in specification in Registration letter for following products.

S. No	Reg. No.	Existing Name of Drug(s) & Composition	Desired corrections	Remarks
I	II	III	IV	V
	069192	Zara tablet Each tablet contains:- Paroxetine Hydrochloride……25mg (BP Specs)	Zara tablet Each **Extended Release** tablet contains:- Paroxetine Hydrochloride....25mg **(USP Specs)**	Approved in USFDA **as 25mg base.**

Documents details as per SOPs:

Sr. No.	Documents submitted by firm
1	Application with required fee as per relevant SRO, if error is on part of firm. Fee Rs. 5000/- deposited dated 25-02-2019
2	Copy of registration letter and last renewal status.
3	Documents in support of proposed correction

4	Analytical reports as per monograph of FPP
	Undertaking that : i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum / court of law regarding this product. iii. 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. iv. The provided information/ documents are true/ correct**.**

Decision: Registration Board deferred the case as the evidence of approval of the applied formulation could not be confirmed from RRAs.

Case No. 106: 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 Each 4ml ampoule contains:- Choline Alfoscerate …….1000mg Manufactured by M/s. Italfarmaco S.P.A. Itlay Approved in Italy (AIFA) New proposed brand names:- 1. Hilatin 2. Neurotin 3. Neulotin	Registration board deferred request of M/s. Himont Pharmaceuticals (Pvt.) Limited Lahore **for latest NOC from Exporter**.	Now the firm submitted latest NOC from Manufacturer 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 of 288th Meeting:
Registration Board deferred the case for evaluation of dossier.

The firm has submitted following documents:-
i. Copy of application with Rs.42000/- (**copy** challan) submitted on 10.02.2015 and **copy** Rs.20000/- dated 17.12.2012.
ii. Copy of registration letter for import dated 29.08.1999.
iii. Copy of Form-5
iv. Copy of GMP inspection report dated 4th and 5th October, 2018
v. NOC from M/s Italfarmaco S.P.A Italy dated **28-01-2019**
vi. Evidence for section approval

Decision: Registration Board approved transfer of registration of the above product from import to local manufacturer i.e. M/s. Himont Pharmaceuticals, Lahore. Firm shall propose alternate brand name as present name is not authorized by manufacturer / marketing authorization holder. Fee shall be verified as per procedure adopted by Registration Board.

COMPLETE CASES

i. Local manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Genix Pharma (Pvt) Ltd, 44, 45-B, Korangi Creek Road, Karachi						
1.	076025	Hb-One Injection 100mg Each ml Contains: Iron (III) Isomaltoside 1000 eq. to Iron…100mg	19-09-2013	Dy. No. 25025 dated 18-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-9-2023
2.	076072	Gen-M Injection 30mg Each Vial Contains: Artesunate…30mg	26-09-2013	Dy. No. 25025 dated 18-07-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
3.	076073	Gen-M Injection 120mg Each Vial Contains: Artesunate…120mg	26-09-2013	Dy. No. 25025 dated 18-07-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
M/s. CCL Pharmaceuticals (Pvt) Ltd, 62-Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore						
4.	1842-EX	Cipromen Tablet 500mg Each Film Coated Tablet Contains: Ciprofloxacin HCl eq. to Ciprofloxacin…500mg	04-09-2013	Dy. No. 22817 dated 02-07-2018 10000/-	03-09-2023	w.e.f. 04-09-2018 to 03-09-2023
5.	1843-EX	Cipromen Tablet 250mg Each Film Coated Tablet Contains: Ciprofloxacin HCl eq. to Ciprofloxacin…250mg	04-09-2013	Dy. No. 22817 dated 02-07-2018 10000/-	03-09-2023	w.e.f. 04-09-2018 to 03-09-2023
6.	1844-EX	T-Sar Plus Tablet Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg	04-09-2013	Dy. No. 22817 dated 02-07-2018 10000/-	03-09-2023	w.e.f. 04-09-2018 to 03-09-2023
7.	1845-EX	DekFer Injection 100mg Each 2ml Contains: Iron Dextran eq. to Elemental Iron…100mg	04-09-2013	Dy. No. 22817 dated 02-07-2018 10000/-	03-09-2023	w.e.f. 04-09-2018 to 03-09-2023
8.	052635	Zeque Tablet 0.25mg Each Tablet Contains: Ropinirole HCl…0.25mg	13-10-2008	Dy. No. 22817 dated 02-07-2018 10000/-	12-10-2023	w.e.f 13-10-2018 to 12-10-2023
9.	052636	Zeque Tablet 1mg Each Tablet Contains: Ropinirole HCl…1mg	13-10-2008	Dy. No. 22817 dated 02-07-2018 10000/-	12-10-2023	w.e.f 13-10-2018 to 12-10-2023
10.	052637	Zeque Tablet 2mg Each Tablet Contains: Ropinirole HCl…2mg	13-10-2008	Dy. No. 22817 dated 02-07-2018 10000/-	12-10-2023	w.e.f 13-10-2018 to 12-10-2023
11.	052638	Epileptal Suspension Each 5ml Contains: Oxcarbazipine…300mg	13-10-2008	Dy. No. 22817 dated 02-7-2018 10000/-	12-10-2023	w.e.f 13-10-2018 to 12-10-2023
12.	052639	Neobonvit Tablet Each Tablet Contains:	13-10-2008	Dy. No. 22817 dated	12-10-2023	w.e.f 13-10-2018 to

		Alendronate Sodium Trihydrate eq. to Alendronic Acid…70mg Cholecalciferol (Vit.D3)…70mcg		02-07-2018 10000/-		12-10-2023
13.	052640	Sucrofer-F Tablet Each Tablet Contains: Iron Protein Succinylate 400mg eq. to Elemental Iron…20mg Folic Acid…2.5mg	13-10-2008	Dy. No. 22817 dated 02-07-2018 10000/-	12-10-2023	w.e.f 13-10-2018 to 12-10-2023
M/s. Radiant Pharma (Pvt) Ltd., 43-E Sundar Industrial Estate, Sundar Raiwind Road, Lahore						
14.	076954	Radimether Tablets Each tablet contains: Artemether….40mg, Lumefantrine….240mg	26-07-2013	Dy. No. 24173 dated 12-07-2018 10000/-		Deferred for clarification as firm responded that they are manufacturing film coated tablets; however the reference formulation is uncoated.
15.	076955	Radikast Tablets Each tablet contains: Montelukast as sodium…..10mg	26-07-2013	Dy. No. 24173 dated 12-07-2018 10000/-	25-07-2023	w.e.f. 26-07-2018 to 25-07-2023
M/s. Fynk Pharmaceuticals, 19-Km G.T. Road, KalashahKaku, Lahore						
16.	050921	Alfacidol Tablets. Each Tablet contains: Alfacalcidol..0.5mcg	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
17.	050922	Atorin Tablets. Each Tablet contains: Atorvastatin……..10mg.	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
18.	050923	Atorin Tablets. Each Tablet contains: Atorvastatin…….20mg.	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
19.	050925	Dispel DS Suspension Each 5ml contains: Cefixime……200mg. (USP Specs)	04-08-2008 Change of brand name dated: 05-05-2011	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
20.	050926	Dizole DS Tablet Each Tablet contains: Diloxanide Furoate ……..500mg. Metronidazole ……400mg.	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
21.	050927	Drospa Tablets 40mg. Each Tablet contains: Drotaverine HCl……..40mg.	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
22.	050928	Fitidine Tablets. Each Tablet contains: Cimetidine…….400mg. (B.P Specs)	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
23.	50929	Fycam Tablets. Each Tablet contains: Piroxicam……...10mg.	04-08-2008	Dy. No. 25931 dated 27-07-2018	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023

				10000/-		
24.	050930	Fymide Tables. Each Tablet contains: Frusemide……..40mg. (B.P Specs)	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
25.	050931	Fynklocin Tablets. Each Tablet contains: Norfloxacin……400mg (B.P Specs)	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
26.	050932	Fynkomether Tablets. Each Tablet contains: Artemether……20mg. Lumefantrine……..120mg.	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
27.	050933	Idocin Capsules. Each capsule contains: Indomethacin……..25mg. (B.P Specs)	04-08-2008	Dy. No. 25931 dated 27-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
M/s. Ferozsons Laboratories Ltd, Amangarh-Nowshera, KPK						
28.	050817	Combitrol 5/80 Tablet Each Tablet Contains: Amlodipine Besylate…5mg Atorvastatin Calcium…80mg	29-07-2008	Dy. No. 25029 dated 18-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023.
29.	050816	Combitrol 10/20 Tablet Each Tablet Contains: Amlodipine Besylate…10mg Atorvastatin Calcium…20mg	29-07-2008	Dy. No. 25028 dated 18-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023.
30.	050818	Omega Capsule 40mg Each Capsule Contains: Omeprazole as Enteric Coated Pellets…40mg Source: M/s Cadila Healthcare Ltd: 291 GDC Estate, Ankleshwer Gujarat India	29-07-2008	Dy. No. 25030 dated 18-07-2018 20000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023.
31.	050814	Combitrol 5/40 Tablet Each Tablet Contains: Amlodipine Besylate…5mg Atorvastatin Calcium…40mg	29-07-2008	Dy. No. 25031 dated 18-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023.
32.	050815	Combitrol 10/10 Tablet Each Tablet Contains: Amlodipine Besylate…10mg Atorvastatin Calcium…10mg	29-07-2008	Dy. No. 25032 dated 18-07-2018 10000/-	28-07-2023	w.e.f. 9-07-2018 to 28-07-2023.
M/s. Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E., Karachi						
33.	020985	Lanzol 15 Capsule Each Capsule Contains: Lansoprazole…15mg Source: Nosch Labs Pvt Limited, D. No.5-5-35/33/3, Prashanti Nagar I.E Kukatpally Hyderabad-500 072, India	11-09-98	Dy. No. 26034 dated 30-07-2018 20000/-	10-09-2023	w.e.f. 1-09-2018 to 10-09-2023
34.	076001	Montec 4mg Tablet Each Chewable Tablet Contains: Montelukas Sodium eq. to Montelukast…4mg	19-09-13	Dy. No. 26033 dated 30-07-2018 10000/-	18-09-2023	w.e.f 19-09-2018 to 18-09-2023
35.	020984	Reltus C&F Syrup Each 5ml Contains: Paracetamol…80mg Pseudoepherine HCl…15mg Chlorpheniramine Maleate…1mg	11-09-98	Dy. No. 26033 dated 30-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023

36.	4222-EX	Nalphar Injection Each ml Contains: Naloxone HCl…0.4mg	22-08-13	Dy. No. 26033 dated 30-07-2018 10000/-	21-08-2023	w.e.f. 22-08-2018 to 21-08-2023
M/s. Lowitt Pharma (Pvt) Ltd, Plot No. 24-Industrial Estate, Hayatabad, Peshawar						
37.	50987	Lowcit 20mg Tablet Each film coated Tablet contains: Citalopram as HBr…….20mg. (USP Specs)	12-08-2008 Change of brand name dated 01-01-2011	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
38.	50988	Lowpime Injection 1gm IV/IM. Each vial contains: Cefepime as HCl……1gm. (USP Specs)	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
39.	50990	Sulcef Injection 1gm IV/IM. Each vial contains: Cefoperazone as Sodium...500mg. Sulbactam as Sodium …….500mg.	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
40.	50991	Motedone Tablets. Each film coated Tablet contains: Domperidone Maleate…….10mg. (BP Specs)	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
41.	50992	EC-Pram Tablets. Each film coated Tablet contains: Escitalopram ……..10mg.	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
42.	50993	Lowtral 100mg Tablets. Each film coated Tablet contains: Sertraline as HCl……..100mg.	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
43.	50994	Olan-Z Tablets. Each film coated Tablet contains: Olanzapine……..5mg.	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
44.	50995	Lomec Tablets 500mcg. Each film coated Tablet contains: Mecobalamine……..500mcg.	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
45.	50996	Sulcef Injection 2gm IV/IM. Each vial contains: Cefoperazone as Sodium…....1gm. Sulbactum as Sodium ……1gm	12-08-2008	Dy. No. 26185 dated 30-07-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
M/s Bryon Pharmaceuticals (Pvt) Ltd, 48-Hayatabad Industrial Estate, Peshawar						
46.	050941	Cycloram 20mg Tablet Each tablet contains: Piroxicam Beta Cyclodextrin eq. to Piroxicam ……. 20mg	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
47.	050942	Losaten-H Tablet Each tablet contains: Losartan Potassium……50mg Hydrochlorothiazide …12.50mg	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
48.	050943	Gemicin Tablet Each tablet contains: Gemifloxacin Mesylate 400mg eq. to Gemifloxacin …… 320mg	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023

49.	050944	Corsafe AT 5/10 Tablet Each film coated tablet contains: Amlodipine (Besylate) … 5mg Atorvastatin (as Calcium Salt)….10mg	05-08-2008 Change of brand name dated 24-03-2010	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
50.	050945	Mexcel 15mg Tablet Each tablet contains: Meloxicam …….. 15mg (B.P Specs)	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
51.	050946	Mexcel 7.5mg Tablet Each tablet contains: Meloxicam ……. 7.5mg (B.P Specs)	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
52.	050947	Leoflox 250mg Tablet Each film coated tablet contains: Levofloxacin hemidydrate eq. to Levofloxacin …… 250mg	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
53.	050948	Leoflox 500mg Tablet Each film coated tablet contains: Levofloxacin hemidydrate eq. to Levofloxacin …….. 500mg	05-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
54.	051146	Mucorent Expectorant Each 5ml contains: Terbutaline Sulphate ……..1.5mg. Guaiphenesin ……..66.5mg.	28-08-2008	Dy. No. 25528 dated 23-07-2018 10000/-	27-08-2023	w.e.f. 28-08-2018 to 27-08-2023
M/s Mediate Pharmaceuticals Pvt Limited, 150-151 Sector 24, Korangi Industrial Area Karachi						
55.	050407	Mediryl 3mg Tablet Each tablet contains: Glimepride... 3mg	07-08-2008	Dy. No. 25517dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
56.	050411	Valstrate 80mg Tablet Each tablet contains: Valsartan…….80mg	07-08-2008	Dy. No. 25516 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
57.	050415	Hyporose 20mg Tablet Each tablet contains: Rosuvastatin (as Calcium)…20mg	07-08-2008	Dy. No. 25520 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
58.	050410	Kardo 8mg Tablet Each tablet contains: Candesartan Cilexetil…….8mg	07-08-2008	Dy. No. 25518 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
59.	050409	Kardo 16mg Tablet Each tablet contains: Candesartan Cilexetil ……..16mg	07-08-2008	Dy. No. 25519 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
60.	050412	Valstrate 160mg Tablet Each tablet contains: Valsartan…….160mg	07-08-2008	Dy. No. 25515 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
61.	050408	Lexotec 3mg Tablet Each tablet contains: Bromazepam……... 3mg	07-08-2008	Dy. No. 25521 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
62.	050414	Hyporose 10mg Tablet Each tablet contains: Rosuvastatin (as Calcium)…10mg	07-08-2008	Dy. No. 25513 dated 23-07-2018	06-08-2023	w.e.f 07-08-2018 to 06-08-2023

				10000/-		
63.	050413	Hyporose 5mg Tablet Each tablet contains: Rosuvastatin (as Calcium)…5mg	07-08-2008	Dy. No. 25514 dated 23-07-2018 10000/-	06-08-2023	w.e.f 07-08-2018 to 06-08-2023
M/s. ATCO Laboratories Ltd., B-18, S.I.T.E., Karachi						
64.	50522	XMG 0.25mg Tablet Each film coated tablet contains: Ropinirole (As HCl)….0.25mg	29-08-2008	Dy. No. 25930 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
65.	50523	XMG 1mg Tablet Each film coated tablet contains: Ropinirole (As HCl)…….1mg	29-08-2008	Dy. No. 25930 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
66.	50524	XMG 2mg Tablet Each film coated tablet contains: Ropinirole (As HCl)…….2mg	29-08-2008	Dy. No. 25930 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
67.	50525	Adapco Gel Each gm contains: Adapalene……0.1%w/w	29-08-2008	Dy. No. 25930 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
68.	50526	Adapco Cream Each gm contains: Adapalene……0.1%w/w	29-08-2008	Dy. No. 25930 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
69.	30298	Cardnit 2.6mg Tablets Each tablet contains: Glyceryl Trinitrate 2.6mg	26-08-2003	Dy. No. 25929 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
70.	30299	Cardnit 6.4mg Tablets Each tablet contains: Glyceryl Trinitrate 6.4mg	26-08-2003	Dy. No. 25929 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
71.	50520	Acspot Gel Each gm contains: Isotretinoin…..0.05%w/w	29-08-2008	Dy. No. 25929 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
72.	50521	Rovator 5mg Tablet Each film coated tablet contains: Rosuvastatin (as Calcium). ….5mg	29-08-2008	Dy. No. 25929 dated 27-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
M/s. Leads Pharma (Pvt) Ltd, Plot No. 81-A, Street No. 6, I-10/3, Islamabad						
73.	050950	G-Flox Tablets. Each Tablet Contains: Gemifloxacin……320mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
74.	050951	Famoleads Tablets 40mg. Each Tablet Contains: Famotidine ……40mg. (B.P Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
75.	050952	Famoleads Tablets 20mg. Each Tablet Contains: Famotidine ……20mg. (B.P Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
76.	050953	Diclosoft- K Tablets 75mg. Each Tablet Contains:	06-08-2008	Dy. No. 25823 dated	05-08-2023	w.e.f. 06-08-2018 to

		Diclofenac Potassium…….75mg. (B.P Specs)		26-07-2018 10000/-		05-08-2023
77.	050954	Diclosoft - K Tablets 50mg. Each Tablet Contains: Diclofenac Potassium…….50mg. (B.P Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
78.	050955	Diclosoft 50mg Tablets. Each Tablet Contains: Diclofenac Sodium…….50mg. (B.P Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
79.	050956	Allergofex Tablets 180mg. Each Tablet Contains: Fexofenadine HCl……180mg. (USP Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
80.	050957	Allergofex Tablets 120mg. Each Tablet Contains: Fexofenadine HCl……120mg. (USP Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
81.	050958	Allergofex Tablets 60mg. Each Tablet Contains: Fexofenadine HCl……60mg. (USP Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
82.	050959	Rabizole Tablets 20mg. Each Tablet contains: Rabeprazole Sodium...20mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
83.	050960	Rabizole Tablets 10mg. Each Tablet contains: Rabeprazole Sodium…10mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
84.	050961	Nexronap Tablet 550mg Each Tablet contains: Naproxen Sodium USP……..550mg. (B.P Specs)	06-08-2008 Change of brand name 29-12-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
85.	050962	Nexronap Tablet 275mg Each Tablet contains: Naproxen Sodium USP……..275mg. (B.P Specs)	06-08-2008 Change of brand name : 29-12-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
86.	050963	Paraleine Tablets. Each Tablet contains: Paracetamol……..500mg. Caffeine……..65mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
87.	050964	Cytamic Tablet 500mcg Each Tablet Contains: Mecobalamin …….500mcg.	06-08-2008 Change of brand name : 28-05-2009	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
88.	050965	Monty Tablets. Each Tablet Contains: Montelukast as Sodium…….10mg. (USP Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
89.	050966	Monty Tablets. Each Tablet Contains: Montelukast as Sodium…….5mg. (USP Specs)	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
90.	050967	Lo-K Tablets 25mg. Each Tablet contains: Losartan Potassium……25mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023

				10000/-		
91.	050968	Lo-K Tablets 50mg. Each Tablet contains: Losartan Potassium…50mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
92.	050969	Glucoarthi Tablet Each Tablet Contains: Glucosamine Sulphate……500mg Chondroiton Sulphate….400mg.	06-08-2008 Change of brand name 29-12-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
93.	050970	G-Pentin Capsules 400mg. Each Capsule Contains: Gabapentin….400mg	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
94.	050971	G-Pentin Capsules 300mg. Each Capsule Contains: Gabapentin…….300mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
95.	050972	G-Pentin Capsules 100mg. Each Capsule Contains: Gabapentin…….100mg.	06-08-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
96.	050973	Fungeez Capsule 50mg Each Capsule Contains: Fluconazole ……50mg. (USP Specs)	06-08-2008 Change of brand name 29-12-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
97.	050974	Fungeez Capsule 150mg Each Capsule Contains: Fluconazole ……150mg. (USP Specs)	06-08-2008 Change of brand name 29-12-2008	Dy. No. 25823 dated 26-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad						
98.	052552	Tasilex Tablets 75mg. Each Tablet contains: Diclofenac Potassium…….75mg.	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
99.	052553	Tasilex Tablets 50mg. Each Tablet contains: Diclofenac Potassium…….50mg.	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
100.	052554	Glemser Tablets 4mg. Each Tablet contains: Glimepride…….4mg.	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
101.	052555	Glemser Tablets 2mg. Each Tablet contains: Glimepride……..2mg.	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
102.	052556	Glemser Tablets 1mg. Each Tablet contains: Glimepride……1mg.	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
103.	052557	Panlex Tablets 40mg. Each enteric coated Tablet contains: Pantoprazole Sodium Sesquihydrate eq. to Pantoprazole…….40mg.	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
104.	052560	Zithin Tablets 250mg. Each Tablet contains: Azithromycin as Dihydrate	23-09-2008	Dy. No. 25890 dated 27-07-2018	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023

		……250mg. (USP Specs)		10000/-		
105.	052561	Difnac Tablets 50mg. Each Tablet contains: Diclofenac Sodium …….50mg. (B.P Specs)	23-09-2008	Dy. No. 25890 dated 27-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
M/s. Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase III, Industrial Estate, Hattar						
106.	30784	Clavorin Injection Each Vial Contains: Clarithromycin (as Lactobionate)…500mg	02-08-2003	Dy. No. 25022 dated 18-07-2018 10000/-		Deferred for clarification of manufacturing facility by the firm.
107.	30786	Cataplas Injection Each ml Contains: Artemether…80mg	02-08-2003	Dy. No. 25022 dated 18-07-2018 10000/-	01-08-2023	w.e.f. 02-08-2018 to 01-08-2023
108.	30787	Plasmocide Tablet 60mg Each Film Coated Tablet Contains: Dihydroartimisinin……60mg	02-08-2003	Dy. No. 25022 dated 18-07-2018 10000/-	01-08-2023	w.e.f. 02-08-2018 to 01-08-2023
109.	1059-EX	Clarmin Tablet 500mg Each Film Coated Tablet Contains: Clarithromycin…500mg	26-08-2008	Dy. No. 25035 dated 18-07-2018 10000/-	25-08-2023	w.e.f. 26-08-2018 to 25-08-2023
M/s. Sami Pharmaceuticals (Pvt) Ltd., Plant F-95, Off. Hub River Road, S.I.T.E., Karachi						
110.	22359	Provas Injection Each 2 ml contains: Paracetaml 300mg	11-09-1998	Dy.No.24175 dated 12-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
111.	9922	Pencit 500mg inj Each vial contains: Sterile Ampicillin Sodium BP equivalent to Anhydrous Ampicillin 250mg Sterile Cloxacillin Sodium BP equivalent to Anhydrous Cloxacillin 250mg	15-09-1988	Dy. No. 24175 dated 12-07-2018 10000/-		Deferred for clarification of manufacturing facility by the firm
112.	76060	Ampisol 50mg tablet Each tablet contains: Amisulpride 50mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
113.	76061	Ampisol 100mg tablet Each tablet contains: Amisulpride 100mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
114.	76059	Ampisol 200mg tablet Each tablet contains: Amisulpride 200mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
115.	76066	Ampisol 400mg tablet Each film coated tablet contains: Amisulpride 400mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
116.	76057	Danilon 10mg tablet Each film coated tablet contains: Dydrogesterone 10mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
117.	76058	Ecasil 100mg/5ml Dry powder Each 5ml of reconstituted suspension	20-09-2013	Dy. No. 24175 dated	19-09-2023	w.e.f. 20-09-2018 to

		contains: Each 5ml of reconstituted suspension contain		12-07-2018 10000/-		19-09-2023
118.	76064	Neo-Antial 0.5mg/ml Syrup Each ml contains: Desloratadine 0.5mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
119.	76065	Neo-Sedil 2.5mg/5ml Syrup Each 5ml contains: Levocetirizine Dihydrochloride 2.5mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
120.	76062	Timequin Tablet Each film coated tablet contains: Dihydroartemisinin 40mg Piperaquine Phosphate 320mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
121.	76063	Timequin Suspension Each 5ml contains: Dihydroartemisinin 15mg Piperaquine Phosphate 120mg	20-09-2013	Dy. No. 24175 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
122.	50746	Omsis 30mg injection Each ml contains: Pentazocine 30mg	26-09-2008	Dy. No. 24175 dated 12-07-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
123.	50745	Mofest tablet Each film coated tablet contains: Moxifloxacin 400mg	26-09-2008	Dy. No. 24175 dated 12-07-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
124.	50744	Montika 4mg sachet Each sachet contains: Montelukast 4mg	26-09-2008	Dy. No. 24175 dated 12-07-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
125.	14423	Klint Suspension Each 5ml contains: Mrtronidazole Benzoate eq to Metronidazole BP 200mg	14-10-1993	Dy. No. 24175 dated 12-07-2018 10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
126.	14422	Klint 400mg tablet Each tablet contains: Metronidazole 400mg	14-10-1993	Dy. No. 24175 dated 12-07-2018 10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
127.	14424	Conspic Laxative drop Each ml contains: Sulfolax 7.5mg	14-10-1993	Dy. No. 24175 dated 12-07-2018 10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
128.	76115	D-Tress Injection Each ml contains: Cholecalciferol 5ml	24-10-2013	Dy. No. 24175 dated 12-07-2018 10000/-	23-10-2023	w.e.f. 24-10-2018 to 23-10-2023
129.	10007	Zolen Suspension Each 10ml contains: Diloxanide Furoate BP 250mg Metronidazole Benzoat 320mg eq to Metronidazole BP 200mg	30-10-1988	Dy. No. 24175 dated 12-07-2018 10000/-	29-10-2023	w.e.f. 30-10-2018 to 29-10-2023
M/s. Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi						
130.	009877	Vidaylin-F Drops Each ml Contains: Fluoride (as Sodium)…0.25mg	19-09-1988	Dy. No. 24371 dated 13-07-2018	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023

		Vitamin A…1500IU Vitamin D…400IU Vitamin B1…0.5mg Vitamin B2…0.6mg Vitamin B6…0.4mg Niacinamide…8mg Vitamin C…35mg Vitamin E…5.00IU		10000/-		
M/s. Linear Pharma, Plot No. 18, Street S-4, National Industrial Zone, (RCCI) Rawat, Islamabad						
131.	075451	Itracure 100mg Capsule Each Capsule Contains: Itraconazole…100mg	04-07-2013	Dy. No. 25639 dated 24-07-2018 20000/-	03-07-2023	w.e.f. 04-07-2018 to 03-07-2023
132.	075450	Linofer Tablets Each tablet contains: Iron(iii) hydroxide polymaltose complex…. 100mg Folic acid....0.35mg	04-07-2013	Dy. No. 25640 dated 24-07-2018 20000/-	03-07-2023	w.e.f. 04-07-2018 to 03-07-2023
M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi						
133.	50586	Erzing 225mg Sachet Each sachet contains: Erdosteine…….225mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
134.	50587	Co-Atorap 10/10 Tablet Each tablet contains: Amlodipine (as Besylate)..10mg Atorvastatin (as Calcium Trihydrate)…….10mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
135.	50588	Co-Atorap 10/20 Tablet Each tablet contains: Amlodipine (as Besylate)..10mg Atorvastatin (as Calcium Trihydrate)…….20mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
136.	50589	Co-Atorap 10/40 Tablet Each tablet contains: Amlodipine (as Besylate)..10mg Atorvastatin (as Calcium Trihydrate)…….40mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
137.	50590	Argent 50 Tablet Each co-blister contains : Each six small tablets contains:- Artesunate…….50mg Each two large tablets contains:- Sulfadoxine…….500mg Pyrimethamine…….25mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
138.	50591	Argent 100 Tablet Each co-blister contains : Each six small tablets contains:- Artesunate…….100mg Each three large tablets contains:- Sulfadoxine……500mg Pyrimethamine……25mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
139.	50593	Xofi Syrup Each ml contains: Doxofylline……20mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
140.	76026	Citanew D 10mg Tablet Each dispersible tablet contains:	19-09-2013	Dy. No. 23574 dated	18-09-2023	w.e.f. 19-09-2018 to

		Escitalopram as Oxalate...10 mg		06-07-2018 10000/-		18-09-2023
141.	76029	Febhil 120mg Tablets Each film coated tablet contains: Febuxostat ……...120mg	19-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
142.	76030	Vilzer-Met 50/1000 Tablets Each film coated tablet contains: Vildagliptin ……..50mg Metformin HCl …….1000mg	19-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
143.	76031	Vilzer-Met 50/850 Tablets Each film coated tablet contains: Vildagliptin ……50mg Metformin HCl …….850mg	19-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
144.	76087	Qusel XR 300mg Tablet Each extended release tablet contains: Quetiapine Fumarate eq. to Quetiapine……..300 mg	26-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
145.	22245	Cravit Tablets Each tablet contains: Levofloxacin as hemihydrate… 250 mg	10-09-1998	Dy. No. 23574 dated 06-07-2018 10000/-	09-09-2023	w.e.f. 10-09-2018 to 09-09-2023
146.	22246	Cravit Tablets 500 Each tablet contains: Levofloxacin as hemihydrate… 500 mg	10-09-1998	Dy. No. 23574 dated 06-07-2018 10000/-	09-09-2023	w.e.f. 10-09-2018 to 09-09-2023
147.	50592	Piozer-G 15/2 Tablets Each tablet contains: Pioglitazone (as HCl)… 15 mg, Glimepride… 2 mg	11-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	10-09-2023	w.e.f 11-09-2018 to 10-09-2023
148.	50689	Artem 40mg Injection Each ml contains: Artemether……..40mg	23-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
149.	50690	Piozer-G 30/2 Tablet Each tablet contains: Pioglitazone (as HCl) …30mg Glimepiride……..2mg	23-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
150.	50691	Piozer-G 30/4 Tablet Each tablet contains: Pioglitazone (as HCl) …30mg Glimepiride……...4mg	23-09-2008	Dy. No. 23574 dated 06-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
151.	76027	Febhil 40mg Tablets Each film coated tablet contains: Febuxostat …….40mg	19-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
152.	76028	Febhil 80mg Tablets Each film coated tablet contains: Febuxostat ……80mg	19-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
153.	76086	Lacolep 10mg/ml Injection Each ml contains: Lacosamide ……10 mg	23-09-2013	Dy. No. 23574 dated 06-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
M/s. Barrett Hodgson Pakistan (Pvt) Ltd, F/423, S.I.T.E. Karachi						
54.	076006	PioBar 15mg Tablet Each tablet contains:	19-09-13	Dy. No. 26313 dated	18-09-2023	w.e.f. 19-09-2018 to

		Pioglitazone……..…15 mg		31-07-2018 10000/-		18-09-2023
55.	076012	Diabold Plus Tablet Each film coated tablet contains: Glimepiride ……2mg Metformin HCl 500mg	19-09-13	Dy. No. 26312 dated 31-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
56.	076011	Diabold Plus Tablet Each film coated tablet contains: Glimepiride ……...1mg Metformin HCl ……...500mg	19-09-13	Dy. No. 26311 dated 31-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
57.	076005	Cefstar 250mg Injection Each Vial Contains: Cefepime Arginine Sterile eq to Cefepime…..250 mg	19-09-13	Dy. No. 26310 dated 31-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
58.	076009	MalEra – Max Tablet Each tablet contains: Artemether……..…80 mg Lumefantrine……..…480 mg	19-09-13	Dy. No. 26309 dated 31-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
59.	076008	PioBar 45mg Tablet Each tablet contains: Pioglitazone…..……...45 mg	19-09-13	Dy. No. 26315 dated 31-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
60.	076007	PioBar 30mg Tablet Each tablet contains: Pioglitazone……..…30 mg	19-09-13	Dy. No. 26314 dated 31-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
M/s. CKD Pharmaceuticals Pakistan (Pvt) Ltd., Plot 50/28 Korangi Industrial Area, Karachi						
61.	010785	Fungazole Cream Contains: Econozole Nitrate...1% w/w	14-10-1993	Dy. No. 24678 dated 16-07-2018 10000/-	13-10-2023	w.e.f 14-10-2018 to 13-10-2023
62.	014411	Triprim Forte Tablet Each Tablet Contains: Sulphamethoxazole…800mg Trimethoprim…160mg	14-10-1993	Dy. No. 24678 dated 16-07-2018 10000/-	13-10-2023	w.e.f 14-10-2018 to 13-10-2023
M/s. Helix Pharma (Pvt) Ltd., Hakimsons House, A-56, S.I.T.E., Manghopir Road, Karachi						
63.	50369	Fotiflox 0.5% Sterile Eye Drops Each ml solution contains: Moxifloxacin (as HCl)…….…5mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
64.	50365	Hidilol 12.5mg Tablet Each film coated tablet contains: Carvedilol……12.5mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
65.	50362	Lipifal Plus Tablet 10/10 Each film coated tablet contains: Atorvastatin (as Calcium) ……10mg Amlodipine (as Besylate) ……10mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
66.	50363	Lipifal Plus Tablet 20/10 Each film coated tablet contains: Atorvastatin (as Calcium) ……20mg Amlodipine (as Besylate) …....10mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
67.	50364	Lipifal Plus Tablet 40/10 Each film coated tablet contains: Atorvastatin (as Calcium) …….40mg Amlodipine (as Besylate) …….10mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
68.	50368	Rexant DS 4mg Tablet	04-08-2008	Dy. No.	03-08-2023	w.e.f.

		Each tablet contains: Tizanidine (as HCl) …….4mg		25642 dated 24-07-2018 10000/-		04-08-2018 to 03-08-2023
69.	50366	Tumacta 10mg Tablet Each film coated tablet contains: Leflunomide……10mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
70.	50367	Tumacta 20mg Tablet Each film coated tablet contains: Leflunomide…….20mg	04-08-2008	Dy. No. 25642 dated 24-07-2018 10000/-	03-08-2023	w.e.f. 04-08-2018 to 03-08-2023
M/s. Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Korangi, Karachi						
171.	9881	Normitab Tablet 50mg Each Tablet Contains: Atenolol …..50mg	19-09-1988 Change of brand name:10-06-1990	Dy. No. 24177 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
172.	76036	Keptiron 250mg Tablet Each film coated tablet contains: Levetiracetam ……..250 mg	19-09-2013	Dy. No. 24177 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
173.	76037	Zynq 20mg Tablet Each dispersible tablet contains: Zinc sulphate monohydrate eq. to Elemental Zinc……..20 mg	19-09-2013	Dy. No. 24177 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
174.	76038	Keptiron 500mg Tablet Each film coated tablet contains: Levetiracetam……..500mg	19-09-2013	Dy. No. 24177 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
175.	76039	Keptiron 750mg Tablet Each film coated tablet contains: Levetiracetam……..750mg	19-09-2013	Dy. No. 24177 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
176.	76040	Bacip 250mg Tablet Each film coated tablet contains: Ciprofloxacin as HCl….250 mg	19-09-2013	Dy. No. 24177 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
M/s. Neomedix, Plot No. 5, N/5, National Industrial Zone Rawat, Islamabad						
177.	50861	Mosart Tablet 20mg/120mg Each Tablet Contains: Artemether…20mg Lumefantrine…120mg	01-08-2008	Dy. No. 26035 dated 30-07-2018 10000/-	31-07-2023	w.e.f. 01-08-2018 to 31-7-2023
178.	51106	Tempnil Tablet 500mg Each Tablet Contains: Paracetamol…500mg	22-08-2008	Dy. No. 26035 dated 30-07-2018 10000/-	21-08-2023	w.e.f. 22-08-2018 to 21-08-2023
179.	51107	Osteoezee Tablet 500mg Each Tablet Contains: Glucosamine Sulphate…500mg	22-08-2008	Dy. No. 26035 dated 30-07-2018 10000/-	21-08-2023	w.e.f. 22-08-2018 to 21-08-2023
M/s. Shaigan Pharmaceuticals (Pvt) Ltd, 14 Km Adyala Road, Post Office Dahgal, Rawalpindi						
80.	051101	Ceradin-250 Capsule Each Capsule Contains: Cephradine…250mg	20-08-2008	Dy. No. 22819 dated 02-07-2018 10000/-	19-08-2023	w.e.f. 20-08-2018 to 19-08-2023
81.	051103	Ceradin-500 Capsule Each Capsule Contains: Cephradine…500mg	20-08-2008	Dy. No. 22819 dated 02-07-2018	19-08-2023	w.e.f. 20-08-2018 to 19-08-2023

				10000/-		
82.	051097	Clozox Lotion Each ml Contains: Clotrimazole…10mg	20-08-2008	Dy. No. 22819 dated 02-07-2018 10000/-	19-08-2023	w.e.f. 20-08-2018 to 19-08-2023
83.	051098	Clozox H Cream Each gm Contains: Clotrimazole…10mg Hydrocortisone…10mg	20-08-2008	Dy. No. 22819 dated 02-07-2018 10000/-	19-08-2023	w.e.f. 20-08-2018 to 19-08-2023
84.	051099	Skab Cream Each gm Contains: Permethrin…50mg	20-08-2008	Dy. No. 22819 dated 02-07-2018 10000/-	19-08-2023	w.e.f. 20-08-2018 to 19-08-2023
85.	014277	Famot-40 Tablet Each Tablet Contains: Famotidine…40mg	05-08-1993	Dy. No. 22818 dated 02-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
86.	051174	Sporay Capsule Delayed Release Each Capsule Contains: Itraconazole…100mg	04-09-2008	Dy. No. 22818 dated 02-07-2018 10000/-	03-09-2023	w.e.f 04-09-2018 to 03-09-2023
87.	051173	Adag Gel Each gm Contains: Adapalene…0.10gm	04-09-2008	Dy. No. 22818 dated 02-07-2018 10000/-	03-09-2023	w.e.f 04-09-2018 to 03-09-2023
88.	051123	Ketowin Lotion Each ml Contains: Ketoconazole…20mg	26-08-2008	Dy. No. 22818 dated 02-07-2018 10000/-	25-08-2023	w.e.f. 26-08-2018 to 25-08-2023
89.	051124	Line Cream Each gm Contains: Lindane…10mg	26-08-2008	Dy. No. 22818 dated 02-07-2018 10000/-	25-08-2023	w.e.f. 26-08-2018 to 25-08-2023
90.	051125	Line Lotion Each ml Contains: Lindane…10mg	26-08-2008	Dy. No. 22818 dated 02-07-2018 10000/-	25-08-2023	w.e.f. 26-08-2018 to 25-08-2023
91.	051197	Skab Lotion Each ml Contains: Permethrin…50mg	11-09-2008	Dy. No. 22818 dated 02-07-2018 10000/-	10-09-2023	w.e.f. 11-09-2018 to 10-09-2023
92.	052522	Siton-Plus Cream Each gm Contains: Flucinolone Acetonide…0.1mg Hydroquinone…40mg Tretinoin…0.5mg	19-09-2008	Dy. No. 22818 dated 02-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
93.	051175	Betax Ophthalmic Solution Each ml Contains: Levobetaxolol (as HCl)…5mg	04-09-2008	Dy. No. 22818 dated 02-07-2018 10000/-	03-09-2023	w.e.f. 04-09-2018 to 03-09-2023
M/s. Universal Pharmaceuticals (Pvt) Ltd., 131-A, Industrial Estate, Hayatabad, Peshawar						
94.	50226	Levatra Tablet 250mg Each Tablet Contains: Levofloxacin…250mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
95.	50227	Levatra Tablet 500mg Each Tablet Contains:	25-07-2008	Dy. No. 24770 dated	24-07-2023	w.e.f 25-07-2018 to

		Levofloxacin…500mg		17-07-2018 10000/-		24-07-2023
196.	50228	Ciplon Tablet 250mg Each Tablet Contains: Ciprofloxacin HCl…250mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
197.	50229	Ciplon Tablet 500mg Each Tablet Contains: Ciprofloxacin HCl…500mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
198.	50231	Ritomac Tablet 500mg Each Tablet Contains: Clarithromycin…500mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
199.	50232	Foquin Tablet Each Tablet Contains: Ofloxacin…200mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
200.	50233	Moxident Tablet Each Tablet Contains: Moxifloxacin HCl…400mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
201.	50234	Unispar Tablet Each Tablet Contains: Sparfloxacin…200mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
202.	50235	Zitolide Tablet Each Tablet Contains: Azithromycin 2H2O…250mg	25-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	24-07-2023	w.e.f 25-07-2018 to 24-07-2023
203.	51005	U-Xib 200mg Capsule Each Capsule Contains: Celecoxib…200mg	12-08-2008	Dy. No. 24770 dated 17-07-2018 10000/-		Deferred for submission of renewal fee as renewal application of 2013 was submitted after due date.
204.	1049-EX	Azithrocide 500mg Capsule Each Capsule Contains: Azithromycin…500mg	24-07-2008	Dy. No. 24770 dated 17-07-2018 10000/-	23-07-2023	w.e.f. 24-07-2018 to 23-07-2023
M/s. Saydon Pharmaceutical Industries (Pvt) Ltd., 77/A-Hayatabad Industrial Estate, Peshawar						
205.	49920	Qindon 500 mg Tablet. Each Tablet contains: Levofloxacin (as hemihydrate)……..500mg	17-07-2008	Dy. No. 24516 dated 16-07-2018 10000/-	16-07-2023	w.e.f 17-07-2018 to 16-07-2023
206.	49921	Qindon 250 mg Tablet Each Tablet contains: Levofloxacin (as hemihydrate)…….250mg	17-07-2008	Dy. No. 24516 dated 16-07-2018 10000/-	16-07-2023	w.e.f 17-07-2018 to 16-07-2023
207.	49922	Exact Tablet 400 mg. Each Tablet contains: Ofloxacin……..400 mg	17-07-2008	Dy. No. 24516 dated 16-07-2018 10000/-	16-07-2023	w.e.f 17-07-2018 to 16-07-2023
208.	30850	Eri-P Forte Tablets Each tablet contains:	25-07-2003	Dy. No. 24516 dated	24-07-2023	w.e.f. 25-07-2018 to

		Ethambutol HCl….275mgRifampicin……..150mgPyrazinamide…….400mgIsoniazide……75mg		16-07-2018 10000/-		24-07-2023
M/s. Surge Laboratories (Pvt) Ltd., 10-Km, Faisalabad Road, Bikhi District, Sheikhupura						
209.	1829-EX	Unitax Injection 250mg Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime…250mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
210.	1830-EX	Unitax Injection 500mg Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime…500mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
211.	1831-EX	Unitax Injection 1gm Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime…1gm	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
212.	1832-EX	Ranicare Injection Each 2ml Ampoul Contains: Ranitidine (as HCl)…50mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
213.	1833-EX	Maxtra Injection 1gm Each Vial Contains: Ceftazidime (as Ceftazidime Pentahydrate)…1gm	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
214.	1834-EX	Maxtra Injection 250mg Each Vial Contains: Ceftazidime (as Ceftazidime Pentahydrate)…250mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
215.	1835-EX	Maxtra Injection 500mg Each Vial Contains: Ceftazidime (as Ceftazidime Pentahydrate)…500mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
216.	1836-EX	Bactof Infusion Each 100ml Vial Contains: Ciprofloxacin HCl eq. to Ciprofloxacin…200mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
217.	1837-EX	Widazole Infusion 500mg Each 100ml Vial Contains: Metronidazole…500mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
218.	1838-EX	Flenazine 25mg Injection Each ml Contains: Fluphenazine Decanoate…25mg	29-08-2013	Dy. No. 24506 dated 16-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
M/s. Hizat Pharmaceutical Industry, 170 Industrial Estate Hayatabad, Peshawar						
219.	30220	Hifluzole 150 Capsule Each Capsule Contains: Fluconazole…150mg	25-07-2003	Dy. No. 25156 dated 19-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
220.	30219	Verpel Suspension Each 5ml Contains: Albendazole…200mg	25-07-2003	Dy. No. 25155 dated 19-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
221.	30218	Verpel Tablet Each Tablet Contains: Albendazole…200mg	25-07-2003	Dy. No. 25154 dated 19-07-2018	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023

				10000/-		
222.	30221	Nonsed Tablet Each Tablet Contains: Loratadine…10mg	25-07-2003	Dy. No. 25153 dated 19-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
M/s. City Pharmaceutical Laboratories, Plot No. 12-A, Sector-5, Korangi Industrial Area, Karachi						
223.	075989	Lansoral 30mg Capsule Each Capsule Contains: Lansoprazole Enteric Coated Pellets eq. to Lansoprazole…30mg Source: M/s Vision Pharma Islamabad.	31-07-2013	Dy. No. 23688 dated 09-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
M/s. Usawa Pharmaceuticals, 146-Special Zone, (Export Processing Zone) Risalpur						
224.	50819	Awarax Tablet Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
225.	50821	Hyporide Tablet Each Tablet Contains: Propranolol HCl…10mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
226.	50822	Awacip Tablet Each Tablet Contains: Ciprofloxacin as HCl…250mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
227.	50823	Lowatec Tablet Each Tablet Contains: Losartan Potassium…50mg Hydrochlorothiazide…12.5mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
228.	50824	Limerid Tablet Each Tablet Contains: Glimepiride…2mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
229.	50826	Quinspar Tablet Each Tablet Contains: Sparfloxacin…100mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-		Deferred for evidence of approval of formulation in RRA by the firm.
230.	50827	U-Sazine Tablet Each Tablet Contains: Clozapine…100mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
231.	50828	Xi-Xicam Tablet 7.5mg Each Tablet Contains: Meloxicam…7.5mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
232.	50829	Xi-Xicam Tablet 15mg Each Tablet Contains: Meloxicam…15mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	29-07-2023	w.e.f. 30-07-2018 to 29-07-2023
M/s. Medizan Laboratories (Pvt) Ltd., Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad						
233.	EX-3061	Medigsic Tablet Each Tablet Contains: Paracetamol…450mg, Orphenadrine Citrate…35mg	08-07-2013	Dy. No. 23434 dated 06-07-2018 10000/-	07-07-2023	w.e.f. 08-07-2018 to 07-07-2023
234.	EX-	Mesovasc-5 Tablet	08-07-2013	Dy. No.	07-07-2023	w.e.f.

	3062	Each Film Coated Tablet Contains: Amlodipine (as Besylate)…5mg		23434 dated 06-07-2018 10000/-		08-07-2018 to 07-07-2023
235.	EX- 3063	Mesovasc-10 Tablet Each Film Coated Tablet Contains: Amlodipine (as Besylate)…10mg	08-07-2013	Dy. No. 23434 dated 06-07-2018 10000/-	07-07-2023	w.e.f. 08-07-2018 to 07-07-2023
236.	EX- 3064	Macrozan 500mg Tablet Each Film Coated Tablet Contains: Azithromycin (as Dihydrate)…500mg	08-07-2013	Dy. No. 23434 dated 06-07-2018 10000/-	07-07-2023	w.e.f. 08-07-2018 to 07-07-2023
237.	EX- 3065	Mezinal Tablet Each Film Coated Tablet Contains: Atenolol…50mg	08-07-2013	Dy. No. 23434 dated 06-07-2018 10000/-	07-07-2023	w.e.f. 08-07-2018 to 07-07-2023
M/s. Akson Pharmaceuticals (Pvt) Ltd., Plot No. 9-B/1 & 2, Sector D-1, Old Industrial Estate, Mirpur, Azad Kashmir						
238.	029937	Aksoxime Suspension 100mg Each 5ml Contains: Cefixime Trihydrate eq. to Cefixime…100mg	10-09-2003 Change of brand name dated: 4-8-2008	Dy. No. 25135 dated 19-07-2018 10000/-	09-09-2023	w.e.f. 10-09-2018 to 09-09-2023
M/s. Pharmevo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi						
239.	4216- EX	Ancozar Plus Tablet Each Tablet Contains: Losartan Potassium…50mg Hydrochlorthiazide…12.5mg	22-08-2013	Dy. No. 25777 dated 24-07-2018 10000/-	21-08-2023	w.e.f. 22-08-2018 to 21-08-2023
240.	50396	Evofix DS Suspension Each 5ml contains: Cefixime (as Trihydrate)….200mg	06-08-2008	Dy. No. 25777 dated 24-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
241.	50397	Metpi 500mg Tablet Each tablet contains: Metformin (as HCl)……500mg Pioglitazone……..15mg	06-08-2008	Dy. No. 25777 dated 24-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
242.	50398	Metpi 850mg Tablet Each tablet contains: Metformin (as HCl)……850mg Pioglitazone……...15mg	06-08-2008	Dy. No. 25777 dated 24-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
243.	22965	Acelar 5mg Tablet Each Tablet Contains: Enalapril Maleate…5mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
244.	25495	Acelar 10mg Tablets Each tablet contains: Enalapril Maleate.....10mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
245.	27191	Acelar 20mg Tablets Each tablet contains: Enalapril Maleate…..20mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
246.	27192	Bongard 5mg Tablet Each tablet contains: Alendronate Sodium…5mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
247.	27193	Bongard 10mg Tablet Each tablet contains:	29-07-2003	Dy. No. 23231 dated	28-07-2023	w.e.f. 29-07-2018 to

		Alendronate Sodium…10mg		05-07-2018 10000/-		28-07-2023
248.	22964	Cerizine Syrup Each 5ml Contains: Cetirizine Dihydrochloride…5mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
249.	22963	Cerizine Tablet Each Tablet Contains: Cetirizine Dihydrochloride…10mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
250.	24710	Mantane 15mg Capsule Each Capsule Contains: Lansoprazole…15mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
251.	24711	Mantane 30mg Capsule Each Capsule Contains: Lansoprazole…30mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/- 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
252.	24712	Limitrol 10mg Tablet Each Tablet Contains: Simvastatin…10mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
253.	26040	Limitrol 20mg Tablet Each Tablet Contains: Simvastatin…20mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
254.	26041	Limitrol 40mg Tablet Each Tablet Contains: Simvastatin…40mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
255.	24713	Nise 100mg Tablet Each Tablet Contains: Nimesulide…100mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
256.	24717	Oxirom Disp. 50mg Tablet Each Dispersable Tablet Contains: Roxithromycin…50mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
257.	24718	Oxirom Disp. 100mg Tablet Each Dispersable Tablet Contains: Roxithromycin…100mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
258.	26039	Oxirom 100mg Tablet Each Tablet Contains: Roxithromycin…100mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
259.	24719	Oxirom 150mg Tablet Each Tablet Contains: Roxithromycin…150mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
260.	24720	Oxirom 300mg Tablet Each Tablet Contains: Roxithromycin…300mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
261.	24714	Securin 2.5mg Tablet Each Tablet Contains:	29-07-2003	Dy. No. 23231 dated	28-07-2023	w.e.f. 29-07-2018 to

		Amlodipine Besylate…2.5mg		05-07-2018 10000/-		28-07-2023
262.	24715	Securin 5mg Tablet Each Tablet Contains: Amlodipine Besylate…5mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
263.	24716	Securin 10mg Tablet Each Tablet Contains: Amlodipine Besylate…10mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
264.	27195	Tansin 50mg Tablet Each film coated tablet contains: Losartan Potassium …50mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
265.	27194	Zinex 5mg Tablet Each tablet contains: Flunarazine Dihydrochloride..5mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
266.	22962	Zoltar 20mg Capsule Each Capsule Contains: Omeprazole…20mg	29-07-2003	Dy. No. 23231 dated 05-07-2018 20000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
M/s Standpharm Pakistan (Pvt) Ltd, 20-Km, Ferozepur Road, Lahore						
267.	014289	Bludol 600mg Tablet Each Tablet Contains : Ibuprofen…600mg	05-08-1993	Dy. No. 25526 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
268.	014290	Larex Tablet Each Tablet Contains: Albendazole…20mg	05-08-1993	Dy. No. 25526 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
269.	014291	Curitol 200mg Tablet Each Film Coated Tablet Contains: Ofloxacin….200mg	05-08-1993	Dy. No. 25526 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
270.	014292	Neuxam 1mg Tablet Each Tablet Contains: Alprazolam…1mg	05-08-1993	Dy. No. 25526 dated 23-07-2018 10000/-		Deferred for confirmation of section form Licensing Division.
271.	014299	Ranax 150mg Tablet Each Tablet Contains: Ranitidine…150mg	05-08-1993	Dy. No. 25526 dated 23-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
M/s Zephyr Pharmatec (Pvt) Ltd., A-39, S.I.T.E. II, Super Highway Karachi						
272.	050527	Aspen 60mg Tablet Each tablet contains: Fexofenadine HCl……..60mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
273.	050528	Aspen 120mg Tablet Each tablet contains: Fexofenadine HCl……120mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
274.	050529	Aspen 180mg Tablet Each tablet contains: Fexofenadine HCl……..180mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023

275.	050530	Moor Chewable 5mg Tablet Each tablet contains: Montelukast (as Sodium)……5mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
276.	050531	Moor 10mg Tablet Each tablet contains: Montelukast (as Sodium)….10mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
277.	050532	Helvin Tablet Each tablet contains: Levocetirizine (as Dihydrochloride)..5mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
278.	050533	Cidic 2% Cream Each one gm contains: Fusidic Acid…….20mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
279.	050534	Crocus 250mg Tablet Each tablet contains: Levofloxacin (as Hemihydrate)...250mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
280.	050535	Crocus 500mg Tablet Each tablet contains: Levofloxacin (as Hemihydrate)..500mg	29-08-2008	Dy. No. 25527 dated 23-07-2018 10000/-	28-08-2023	w.e.f. 29-08-2018 to 28-08-2023
M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. C-208-C-217, Hub Industrial Trading State, District Lasbella Baluchistan.						
281.	031287	CP Zaf Infusion 0.2% w/v Each ml Contains: Ciprofloxacin (as Lactate)…2mg	02-10-03	Dy. No. 26028 dated 30-07-2018 10000/-	01-10-2023	w.e.f. 02-10-2018 to 01-10-2023
M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, A-46, SITE North Karachi.						
282.	031292	Novodol Pills Each Tablet Contains: Levonorgestrel…0.15mg Ethinyl Estradiol…0.03mg	03-10-03	Dy. No. 26032 dated 30-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block-21, Federal "B" Industrial Area, Karachi						
283.	030635	CP Zaf Tablet 250mg Each Tablet Contains: Ciprofloxacin HCl 291.1mg eq. to Ciprofloxacin…250mg	03-10-03	Dy. No. 26218 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
284.	030636	CP Zaf Tablet 500mg Each Tablet Contains: Ciprofloxacin HCl 582.2mg eq. to Ciprofloxacin…500mg	03-10-03	Dy. No. 26219 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
285.	030637	Zafvil Injection 22.7mg/ml Each 2ml Contains: Pheniramine Maleate…45.4mg	03-10-03	Dy. No. 26220 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
286.	030639	Tesmic Tablet Each Tablet Contains: Terbutaline Sulphate…2.5mg	03-10-03	Dy. No. 26221 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
287.	030640	Tesmic Syrup Each ml Contains: Terbutaline Sulphate…0.3mg	03-10-03	Dy. No. 26222 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023

288.	031280	Amdaquin Tablet 150mg Each Tablet Contains: Amodiaquine Base…150mg	03-10-03	Dy. No. 26213 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
289.	031281	Famtaza Tablet 20mg Each Film Coated Tablet Contains: Famotidine…20mg	03-10-03	Dy. No. 26214 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
290.	031282	Famtaza Tablet 40mg Each Film Coated Tablet Contains: Famotidine…40mg	03-10-03	Dy. No. 26215 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
291.	031289	Kanamycin Injection 1gm Each 4ml Contains: Kanamycin Sulphate 1.334gm eq. to Kanamycin…1gm	03-10-03	Dy. No. 26217 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
292.	031291	Nifedil SG Capsule 10mg Each Capsule Contains: Nifedipine…10mg	03-10-03	Dy. No. 26216 dated 31-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
293.	050770	Aczofena Tablet 100mg Each Tablet Contains: Aceclofenac…100mg	06-10-08	Dy. No. 26223 dated 31-07-2018 10000/-	05-10-2023	w.e.f. 03-10-2018 to 02-10-2023
294.	031290	Doxycycline Capsule 100mg Each Capsule Contains: Doxycycline Hyclate 115mg eq. to Doxycycline…100mg	03-10-03	Dy. No. 26030 dated 30-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
295.	031279	Orbanaph Eye Drops Contains: Pheniramine Maleate…0.3% Naphazoline HCl…0.025%	03-10-03	Dy. No. 26029 dated 30-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
296.	053011	Tropum 0.025% Nebuliser Solution Each 2ml Contains: Ipratropium Bromide Monohydrate 0.5218 mg eq. to Ipratropium Bromide…0.50mg	09-10-08	Dy. No. 26031 dated 30-07-2018 10000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
297.	050771	Vofloza Tablet 250mg Each Film Coated Tablet Contains: Levofloxacin (as Hemihydrate)…250mg	06-10-08	Dy. No. 26024 dated 30-07-2018 10000/-	05-10-2023	w.e.f. 06-10-2018 to 05-10-2023
298.	050772	Molinza Tablet Each Tablet Contains: Moxifloxacin (as HCl)…400mg	06-10-08	Dy. No. 26027 dated 30-07-2018 10000/-	05-10-2023	w.e.f. 06-10-2018 to 05-10-2023
299.	014459	Zampra Capsule Each Capsule Contains: Omeprazole…20mg	14-10-93	Dy. No. 26025 dated 30-07-2018 10000/-		Deferred for confirmation of source of pellets from firm.
300.	006969	Adicos Syrup Each 5ml Contains: Aminophylline…32mg Ammonium Chloride…30mg Diphenhydramine…8mg Menthol…0.98mg	09-10-83	Dy. No. 26026 dated 30-07-2018 10000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023

301.	006968	Sep-Gard Liquid Contains: Cetrimide…3% w/v Chlorhexidine Gluconate…0.3% w/v	09-10-83	Dy. No. 26023 dated 30-07-2018 10000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
302.	31276	Polyzaf Ophthalmic Ointment Each gm contains: Bacitracin Zinc USP….12.50mgPolymyxin B Sulphate USP.1.66mg	03-10-2003	Dy. No. 25900 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
303.	31277	Lisna Tablets 5mg Each tablet contains: Lisinopril USP…..5mg	03-10-2003	Dy. No. 25899 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
304.	31278	Lisna Tablets 20mg Each tablet contains: Lisinopril USP…..20mg	03-10-2003	Dy. No. 25896 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
305.	31284	Amikacin Injection 250mg Each 2ml contains: Amikacin Sulphate 334mg eq. to Amikacin…….250mg	03-10-2003	Dy. No. 25893 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
306.	31283	Amikacin Injection 100mg Each 2ml contains: Amikacin Sulphate 133.5mg eq. to Amikacin……..100mg	03-10-2003	Dy. No. 25895 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
307.	31286	Amikacin Injection 1Gm Each 4ml contains: Amikacin Sulphate 1.335gm eq. to Amikacin…….1gm	03-10-2003	Dy. No. 25897 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
308.	31285	Amikacin Injection 500mg Each 2ml contains: Amikacin Sulphate 668mg eq. to Amikacin…….500mg	03-10-2003	Dy. No. 25898 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
309.	30633	Aspisafe Tablets 75mg Each enteric coated tablet contains: Aspirin BP……75mg	03-10-2003	Dy. No. 25903 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
310.	30634	Aspisafe Tablets 150mg Each enteric coated tablet contains: Aspirin BP……150mg	03-10-2003	Dy.# 25894 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
311.	31288	Kanamycin Injection 500mg Each 2ml contains: Kanamycin Sulphate 667mg eq. to Kanamycin…….500mg	03-10-2003	Dy. No. 25901 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
312.	31274	Hydro Sod-Suc Injection 100mg Each vial contains: Hydrocortisone Sodium Succinate 134mg eq. to Hydrocortisone….100mg	03-10-2003	Dy. No. 25904 dated 27-07-2018 10000/-	02-10- 2023	w.e.f. 03-10-2018 to 02-10-2023
313.	31275	Hydro Sod-Suc Injection 250mg Each vial contains: Hydrocortisone Sodium Succinate 335mg eq. to Hydrocortisone….250mg	03-10-2003	Dy. No. 25902 dated 27-07-2018 10000/-	02-10-2023	w.e.f. 03-10-2018 to 02-10-2023
i.	**M/s Medera Pharmaceuticals (Pvt) Ltd, 249/A, Industrial Triangle, Kahuta Road, Islamabad**					
314.	050240	Fusiday Tablet Each tablet contains: Sodium Fusidate 250mg	25-07-2008	Dy. No. 25523 dated 23-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023

315.	050242	Divarex 500 Tablet Each tablet contains: Divalproex Sodium 500mg	25-07-2008	Dy. No. 25523 dated 23-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
316.	050243	Mezicarb Tablet Each tablet contains: Carbamazepine 200mg	25-07-2008	Dy. No. 25523 dated 23-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
317.	050244	Frusa Tablet Each tablet contains: Frusemide 40mg	25-07-2008	Dy. No. 25523 dated 23-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
318.	050245	Diuton-100 Tablet Each tablet contains: Spironolactone 100mg	25-07-2008	Dy. No. 25523 dated 23-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
319.	050246	Medpramine Tablet Each tablet contains: Imipramine HCl 25mg	25-07-2008	Dy. No. 25523 dated 23-07-2018 10000/-	24-07-2023	w.e.f. 25-07-2018 to 24-07-2023
320.	024748	Felaxciam 20mg Capsule Each Capsule Contains: Piroxicam…20mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
321.	017458	Anorol Tablet Each Tablet Contains: Orphenadrine Citrate…35mg Paracetamol…450mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
322.	020258	Clofenac Tablets 75mg Each tablet contains: Diclofenac Sodium.75mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
323.	024750	Amazole Capsule 20mg Each Capsule Contains: Omeprazole Pellets 235mg eq. to Omeprazole…20mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-		Deferred for confirmation of source of pellets
324.	020255	Glomac Tablets 250mg Each tablet contains: Mefenamic Acid...250mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
325.	020256	Glomac Tablets 500mg Each tablet contains: Mefenamic Acid...500mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
326.	022492	Funginil Tablets Each tablet contains: Ketoconazole.....200mg	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	30-07-2023	w.e.f. 31-07-2018 to 30-07-2023
M/s. Adamjee Pharmaceuticals (Pvt) Ltd, Plot-39, Sector-15, Korangi Industrial Area, Karachi						
327.	14275	Ifen-200mg Tablet Each Sugar Coated Tablet Contains: Ibuprofen…200mg	05-08-1993	Dy. No. 22812 dated 02-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
328.	14276	Ifen-400mg Tablet Each Sugar Coated Tablet Contains: Ibuprofen…400mg	05-08-1993	Dy. No. 22812 dated 02-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023

M/s. Curatech Pharma (Pvt) Ltd., 35-Km Multan Road, Lahore						
329.	049467	Melather DS tablets Each tablet contains: Artemether 40mg Lumefantrine 240mg	15-07-2008	Dy. No. 24517 dated 16-07-2018 10000/-	14-07-2023	As due date was on holiday, firm submitted fee on next working day, therefore as per Govt. Instructions, Board granted renewal w.e.f. 15-07-2018 to 14-07-2023.
330.	049466	Zanitech tablet 2mg Each tablet contains: Tizanidine as HCl 2mg	15-07-2008	Dy. No. 24517 dated 16-07-2018 10000/-	14-07-2023	As due date was on holiday, firm submitted fee on next working day, therefore as per Govt. Instructions, Board granted renewal w.e.f. 15-07-2018 to 14-07-2023.
331.	049470	Sudoproxim Tablet Each tablet contains: Ibuprofen 200mg Pseudoephedrine HCl 30mg	15-07-2008	Dy. No. 24517 dated 16-07-2018 10000/-	14-07-2023	As due date was on holiday, firm submitted fee on next working day, therefore as per Govt. Instructions, Board granted renewal w.e.f. 15-07-2018 to 14-07-2023.
332.	049471	Sudoproxim Tablet Each tablet contains: Ibuprofen 400mg Pseudoephedrine HCl..... 60mg	15-07-2008	Dy. No. 24517 dated 16-07-2018 10000/-	14-07-2023	As due date was on holiday, firm submitted fee on next working day, therefore as per Govt. Instructions, Board granted renewal w.e.f. 15-07-2018 to 14-07-2023.
M/s. Focus &Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad						
333.	049295	Fexfad 60mg Tablet Each Tablet Contains: Fexofenadine (as HCl).….60mg	10-07-2008	Dy. No. 23149 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023

334.	049296	Fexfad 120mg Tablet Each Tablet Contains: Fexofenadine (as HCl)…120mg	10-07-2008	Dy. No. 23150 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
335.	049290	Dictum Tablet 50mg Each Tablet Contains: Diclofenac Sodium……50mg	10-07-2008	Dy. No. 23151 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
336.	049292	Arther Tablet Each Tablet Contains: Artemether…20mg Lumefantrine…120mg	10-07-2008	Dy. No. 23152 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
337.	049311	Etel Tablet 10mg Each Tablet Contains: Escitalopram (as Oxalate)…10mg	10-07-2008 Change of brand name dated: 07-08-2009	Dy. No. 23146 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
338.	049310	Etel Tablet 5mg Each Tablet Contains: Escitalopram (as Oxalate)…5mg	10-07-2008 Change of brand name dated: 07-08-2009	Dy. No. 23145 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
339.	49313	Alcal Tablet 0.5mcg Each Tablet Contains: Alfacalcidol…0.5mcg	10-07-2008	Dy. No. 23140 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
340.	49293	Lakas 5mg Tablet Each Tablet Contains: Montelukast as Sodium…5mg	10-07-2008	Dy. No. 23141 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
341.	49316	Loprex 275mg Tablet Each Tablet Contains: Naproxen Sodium…275mg	10-07-2008	Dy. No. 23143 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
342.	49317	Loprex 550mg Tablet Each Tablet Contains: Naproxen Sodium…550mg	10-07-2008	Dy. No. 23144 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
343.	49320	Cephcef Capsule 250mg Each Capsule Contains: Cephradine as Monohydrate…250mg	10-07-2008	Dy. No. 23163 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
344.	49319	Cephcef Capsule 500mg Each Capsule Contains: Cephradine as Monohydrate…500mg	10-07-2008	Dy. # 23162 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
345.	49306	Arther DS Tablet Each Tablet Contains: Artemether…40mg Lumefantrine…240mg	10-07-2008	Dy. No. 23153 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
346.	49301	V-fix Dry Suspension Each 5ml Contains: Cefixime as Trihydrate…100mg	10-07-2008	Dy.# 23167 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
347.	49300	V-fix Capsule 400mg Each Capsule Contains: Cefixime as Trihydrate…400mg	10-07-2008 Change of brand name dated: 28-08-2009	Dy.# 23166 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023

348.	49309	Molodrin Tablet Each Tablet Contains: Paracetamol…450mg Orphenadrine Citrate…35mg	10-07-2008	Dy. No. 23174 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
349.	49322	Muriban Ointment Each gm Contains: Mupirocin…20mg	10-07-2008	Dy. No. 23173 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
350.	49323	Sirulz H Cream Each gm Contains: Fusidic Acid…20mg Hydrocortisone Acetate…10mg	10-07-2008	Dy. No. 23172 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
351.	49302	Clinda-V Vaginal Cream Each gm Contains: Clindamycin as Phosphate…20mg	10-07-2008	Dy. No. 23171 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
352.	49299	Flurulz Capsule 150mg Each Capsule Contains: Fluconazole…150mg	10-07-2008	Dy. No. 23158 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
353.	49298	Ciprulz 500mg Tablet Each Tablet Contains: Ciprofloxacin as HCl…500mg	10-07-2008	Dy. No. 23157 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
354.	49297	Ciprulz 250mg Tablet Each Tablet Contains: Ciprofloxacin as HCl…250mg	10-07-2008	Dy. No. 23156 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
355.	49303	Cloteen-V Cream Each gm Contains: Clotrimazole…20mg	10-07-2008	Dy. No. 23155 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
356.	49312	Alcal Tablet 0.25mcg Each Tablet Contains: Alfacalcidol…0.25mcg	10-07-2008	Dy. No. 23139 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
357.	49305	Mecofar Tablet Each Tablet Contains: Mecobalamin…500mcg	10-07-2008	Dy. No. 23148 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
358.	49304	Urobutin Tablet Each Tablet Contains: Oxybutynin HCl…5mg	10-07-2008	Dy. No. 23147 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
359.	49291	Malt Tablet Each Chewable Tablet Contains: Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron…100mg Folic Acid…0.35mg	10-07-2008	Dy. No. 23154 dated 04-07-2018 10000/-	09-07-2023	w.e.f. 10-07-2018 to 09-07-2023
M/s. Medipak Ltd., 132 Industrial Estate, Kot Lakhpat Lahore						
360.	14261	Purisol Glycine Irrigation Solution Each 1000ml contains: Glycine 15.0g	05-08-1993	Dy. No. 24518 dated 16-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
361.	14262	Medilact-D Solution for Injection Each 1000ml contains: Potassium chloride .0400gm Calcium	05-08-1993	Dy. No. 24518 dated 16-07-2018	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023

		chloride .270gm Sodium chloride 6.00gm Sodium lactate 5% soln .01gm DecxtroseNonohydrate 55gm for parenteral use(equivalent to dextrose anhydrous 50gm)		10000/-		
362.	14263	Purisol ringer's irrigation solution Each 1000ml contains: Sodium chlorid 8.5gm Potassium chloride 0.3gm calcium chloride 2h2o 0.33gm	05-08-1993	Dy. No. 24518 dated 16-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
363.	14264	Purisol NS irrigation solution Each 1000ml contains: Sodium chloride 9.0hm water for injection 1000ml	05-08-1993	Dy. No. 24518 dated 16-07-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
M/s. Unison Chemical Works, P.O. Araian, 15-Km Raiwind Road, Lahore						
364.	050153	Unimet Tablet Each Tablet Contains: Artemether…20mg Lumefantrine…120mg	23-07-2008	Dy. No. 23899 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
365.	050154	Dompro Tablet Each Tablet Contains: Domperidone Maleate…10mg	23-07-2008	Dy. No. 23900 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
366.	050155	Sogo Tablet Each Tablet Contains: Esomeprazole Magnesium Trihydrate eq. to Esomeprazole…40mg	23-07-2008	Dy. No. 23901 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
367.	050156	Uniquin 250mg Tablet Each Tablet Contains: Levofloxacin as Hemihydrate…250mg	23-07-2008	Dy. No. 23902 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
368.	050157	Uniquin 500mg Tablet Each Tablet Contains: Levofloxacin as Hemihydrate…500mg	23-07-2008	Dy. No. 23903 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
369.	050158	Clantone Tablet 250mg Each Tablet Contains: Clarithromycin…250mg	23-07-2008	Dy. No. 23904 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
370.	050159	Clantone Tablet 500mg Each Tablet Contains: Clarithromycin…500mg	23-07-2008	Dy. No. 23905 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
371.	050160	Sarix Tablet 250mg Each Tablet Contains: Ciprofloxacin HCl…250mg	23-07-2008	Dy. No. 23906 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
372.	050161	Sarix Tablet 500mg Each Tablet Contains: Ciprofloxacin HCl…500mg	23-07-2008	Dy. No. 23907 dated 10-07-2018 10000/-	22-07-2023	w.e.f. 23-07-2018 to 22-07-2023
M/s. Getz Pharma (Pvt) Ltd, 29-30/27, Korangi Industrial Area, Karachi						
373.	050682	Sodium Chloride 0.9%w/v Solution 5ml Each ml Contains: Sodium Chloride in Water for Injection…0.9%	20-09-2008	Dy. No. 24165 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
374.	050683	Sodium Chloride 0.9%w/v Solution	20-09-2008	Dy. No.	19-09-2023	w.e.f.

		10ml Each ml Contains: Sodium Chloride in Water for Injection…0.9%		24165 dated 12-07-2018 10000/-		20-09-2018 to 19-09-2023
375.	050684	Sodium Chloride 0.9%w/v Solution 15ml Each ml Contains: Sodium Chloride in Water for Injection…0.9%	20-09-2008	Dy. No. 24165 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
376.	050685	Sodium Chloride 0.9%w/v Solution 20ml Each ml Contains: Sodium Chloride in Water for Injection…0.9%	20-09-2008	Dy. No. 24165 dated 12-07-2018 10000/-	19-09-2023	w.e.f. 20-09-2018 to 19-09-2023
377.	022349	Fungicid 50mg Capsule Each Capsule Contains: Fluconazole…50mg	11-09-1998	Dy. No. 24166 dated 12-07-2018 10000/-	10-09-2023	w.e.f 11-09-2018 to 10-09-2023
378.	022350	Fungicid 150mg Capsule Each Capsule Contains: Fluconazole…150mg	11-09-1998	Dy. No. 24166 dated 12-07-2018 10000/-	10-09-2023	w.e.f 11-09-2018 to 10-09-2023
379.	022351	Fungicid 200mg Capsule Each Capsule Contains: Fluconazole…200mg	11-09-1998	Dy. No. 24166 dated 12-07-2018 10000/-	10-09-2023	w.e.f 11-09-2018 to 10-09-2023
380.	050711	Enteca 0.5mg Tablet Each Film Coated Tablet Contains: Entecavir (as Monohydrate)…0.5mg	23-09-2008	Dy. No. 24164 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
381.	050712	Enteca 1mg Tablet Each Film Coated Tablet Contains: Entecavir (as Monohydrate)…1mg	23-09-2008	Dy. No. 24164 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
382.	050719	Olmietec 40mg/12.5mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Hydrochlorothiazide…12.5mg	23-09-2008	Dy. No. 24163 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
383.	050720	Olmietec 40mg/25mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Hydrochlorothiazide…25mg	23-09-2008	Dy. No. 24163 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
384.	050721	Olmietec 20mg/12.5mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg Hydrochlorothiazide…12.5mg	23-09-2008	Dy. No. 24163 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
385.	050715	Olmie 5mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…5mg	23-09-2008	Dy. No. 24162 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
386.	050716	Olmie 10mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…10mg	23-09-2008	Dy. #24162 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
387.	050717	Olmie 20mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…15mg	23-09-2008	Dy. No. 24162 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023

388.	050718	Olmie 40mg Tablet Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg	23-09-2008	Dy. No. 24162 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
389.	050395	Co-Tasmi 80mg/25mg Tablet Each Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…25mg	06-08-2008 Change of brand name 24-09-2008	Dy. No. 24161 dated 12-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
390.	050394	Co-Tasmi 80mg/12.5mg Tablet Each Tablet Contains: Telmisartan…80mg Hydrochlorothiazide…12.5mg	06-08-2008 Change of brand name 24-09-2008	Dy. No. 24160 dated 12-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
391.	050393	Co-Tasmi 40mg/12.5mg Tablet Each Tablet Contains: Telmisartan…40mg Hydrochlorothiazide…12.5mg	06-08-2008 Change of brand name 24-09-2008	Dy. No. 24159 dated 12-07-2018 10000/-	05-08-2023	w.e.f. 06-08-2018 to 05-08-2023
392.	050713	Zoliget 30mg/2mg Tablet Each Tablet Contains: Pioglitazone (as HCl)…30mg Glimepiride…2mg	23-09-2008	Dy. No. 24155 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
393.	050714	Zoliget 30mg/4mg Tablet Each Tablet Contains: Pioglitazone (as HCl)…30mg Glimepiride…4mg	23-09-2008	Dy. No. 24156 dated 12-07-2018 10000/-	22-09-2023	w.e.f. 23-09-2018 to 22-09-2023
394.	076024	M-Low Plus 10mg/12.5mg Tablet Each Tablet Contains: Amlodipine as Besylate…10mg Hydrochlorothiazide…12.5mg	19-09-2013	Dy. No. 24154 dated 12-07-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
395.	50747	Mebever MR 200mg Capsule Each Capsule Contains: Mebeverine HCl as Extended-Release Pellets eq. to Mebeverine HCl…200mg **Source:** M/s RA Chem Pharma Limited, Clinical Research and Bioscience India Pvt Limited, India.	26-09-2008 Change of source dated:5-5-2009	Dy. No. 24153 dated 12-07-2018 20000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
396.	50643	Reventa-Plus Tablet Each Tablet Contains: Alendronate Sodium…70mg Cholecalciferol eq. to Vitamin D3…0.0712mg	17-09-2008	Dy. No. 24149 dated 12-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
397.	50645	Ferotein Chewable Tablet Each Tablet Contains: Iron Protein Succinylate…400mg {eq. to Iron (Fe+3) 20mg} Folic Acid…2.5mg	17-09-2008	Dy. No. 24148 dated 12-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
398.	50650	Moxiget 400mg/250ml Injection Each Vial of 250ml Contains: Moxifloxacin (as HCl)…400mg	17-09-2008	Dy. # 24150 12-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
399.	50651	Nexum IV 40mg Injection Each Vial Contains: Esomeprazole (as Sodium)…40mg	17-09-2008	Dy. No. 24151 dated 12-07-2018 20000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023

400.	50653	Panslay 75mg/3ml Injection Each 3ml Ampoule Contains: Diclofenac Sodium…75mg	17-09-2008	Dy. No. 24147 dated 12-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
401.	50647	Insuget-R Regular Injection Each ml Contains: Human Insulin…100IU	17-09-2008	Dy. No. 24129 dated 11-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
402.	50648	Insuget-N NPH Injection Each ml Contains: Human Insulin…100IU	17-09-2008	Dy. No. 24131 dated 11-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
403.	50649	Insuget-30/70 Injection Each ml Contains: Human Insulin…100IU	17-09-2008	Dy. No. 24130 dated 11-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
404.	53039	Sterile Water for Injection 2ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
405.	53040	Sterile Water for Injection 4ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
406.	53041	Sterile Water for Injection 5ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
407.	53042	Sterile Water for Injection 8ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
408.	53043	Sterile Water for Injection 10ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
409.	53044	Sterile Water for Injection 20ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
410.	53045	Sterile Water for Injection 25ml	29-10-2008	Dy. No. 26021 dated 27-07-2018 10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
411.	22321	Sterile Water for Injection 1ml	13-10-1998	Dy. No. 26019 dated 27-07-2018 10000/-	12-10-2023	w.e.f. 13-10-2018 to 12-10-2023
412.	50654	Nervon 500mcg/ml Injection EACH 1ML AMPOULE CONTAINS : Mecobalamin…500mcg	17-09-2008	Dy. #26018 27-07-2018 10000/-	16-09-2023	w.e.f 17-09-2018 to 16-09-2023
413.	76090	Tenofo-Em Tablet Each Film Coated Tablet Contains: Tenofovir Disoproxil fumarate eq. to245mg Tenofivir Disporoxil Fumartat ……300mg Emtricitabine……200 mg	30-09-2013	Dy. No. 26020 dated 27-07-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023

M/s. Zanctok Pharmaceutical Laboratories, Factory F/5 S.I.T.E. Area Hyderabad						
414.	31001	Promethazine HCl Syrup Each 5ml contains: Promethazine HCl……5mg	26-08-2003	Dy. No. 25641 dated 24-07-2018 10000/-	25-08-2023	w.e.f. 26-08-2018 to 25-08-2023
415.	31002	Win-Sanic Suspension Each 5ml contains: Sucralfate USP……1gm	26-08-2003	Dy. No. 25641 dated 24-07-2018 10000/-	25-08-2023	w.e.f. 26-08-2018 to 25-08-2023
416.	22116	Ammonium Chloride Cough Syrup Each 5ml Contains: Ammonium Chloride…100mg Sodium Citrate…58mg Chlorpheniramine Maleate…2mg Menthol…1mg	31-08-1998	Dy. No. 25641 dated 24-07-2018 10000/-	30-08-2023	w.e.f. 31-08-2018 to 30-08-2023
417.	22117	Kaolin Poultice Each 1000gm Contains: Kaolin Heavy…527g Boric Acid…45g Methyl Salicylate…2ml Mentha Oil…0.5ml Thymol…0.5g Glycerol…425g	31-08-1998	Dy. No. 25641 dated 24-07-2018 10000/-	30-08-2023	w.e.f. 31-08-2018 to 30-08-2023

ii. Local Manufacturing (Veterinary).

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Prix Pharmaceutica (Pvt) Ltd., Plot No. 5-Pharmacity, 30-Km Multan Road, Lahore.						
418.	10706	Diasul-S Water Soluble Powder Each gm Contains: Sulphaquinoxaline Sodium…160mg Diaveridine…40mg Vitamin K3 (Menadiol Sodium Phosphate)…5mg	29-07-2008	Dy. No. 22805 dated 02-07-2018 10000/-	28-07-2023	w.e.f. 29-07-2018 to 28-07-2023
419.	49516	Neo 720 Water Soluble Powder Each gm Contains: Neomycin Sulphate…720mg	30-07-2008	Dy. No. 22806 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
420.	49518	Zuril 2.5% Oral Solution Each 100ml Contains: Toltrazuril…2.5gm	30-07-2008	Dy. No. 22807 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
421.	49519	Metavit Super Water Soluble Powder Each Kg Contains: Retinol Acetate Concentrate (Vitamin A)…20,000,000IU Alfacalcidol (Vitamin D3)…5,000,000IU Alpha Tocopheryl Acetate (Vitamin E)…5500IU Menadiol Sodium Phosphate (Vitamin K3)…3000mg Thiamine HCl (Vitamin B1) …2000mg	30-07-2008	Dy. No. 22808 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023

		Riboflavin Sodium Phosphate (Vitamin B2)...3500mg Niacin (Nicotinic Acid, VitaminB3 Analogue)...20,000mg Pantothenic Acid (Dexpanthenol, Vitamin B5)...6600mg Pyridoxine HCl (Vitamin B6)...3600mg Cyanocobalamin (Vitamin B12)...20mg L-Ascorbic Acid (Vitamin C)...20,000mg Folic Acid...400mg DL-Methionine...10,000mg				
422.	49520	Colimac Water Soluble Powder Each gm Contains: Colistin Sulphate…2,500,000IU	30-07-2008	Dy. No. 22810 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
423.	49521	FLO NEO Water Soluble Powder Each kg Contains: Neomycin Sulfate…285.9gm	30-07-2008	Dy. No. 22810 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
424.	49522	TC Dox Water Soluble Powder Each 100gm Contains: Tylosin Tartrate…10gm Colistin Sulfate…25,000,000IU Doxycycline (as Hyclate)…10gm	30-07-2008	Dy. No. 22810 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
425.	49525	Pancox Soluble Powder Each gm Contains: Sulphamerazine (as Sodium)…200mg Sulfaquinoxaline (as Sodium)…25mg Pyrimethamine…25mg Oxytetyracycline (as HCl)…100mg Vitamin A (Retional Concentrate (Powder)…15,000IU Vitamin K3 (Menadiol Sodium Phosphate)…5mg	30-07-2008	Dy. No. 22809 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
426.	49526	Tylo-Doxicol Water Soluble Powder Each Kg Contains: Tylosin Tartrate…140gm Colistin Sulphate…1200MIU Doxycycline HCl…160gm	30-07-2008	Dy. No. 22811 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
427.	49527	2-OX Oral Drench Each ml Contains: Oxyclozanide…62.50mg Oxfendazole…22.65mg	30-07-2008	Dy. No. 22811 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
428.	49528	2-OX Forte Oral Drench Each ml Contains: Oxyclozanide…62.50mg Oxfendazole…22.65mg Cobalt (as Sulphate)…1.67mg Selenium (as Sodium Selenite)…0.5mg	30-07-2008	Dy. No. 22811 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023

429.	49529	Dicox Forte Water Soluble Powder Each gm Contains: Amprolium (As Hydrochloride)…175mg Sulfaquinoxaline (As Sodium)…175mg Vitamin A (Retinol Concentrate Powder)…15,000IU Vitamin K3 (Menadiol Sodium Phosphate)…5mg	30-07-2008	Dy. No. 22804 dated 02-07-2018 10000/-	29-07-2023	w.e.f 30-07-2018 to 29-07-2023
M/s. Selmore Pharmaceuticals (Pvt) Ltd., 36-Km Multan Road, Lahore						
430.	29665	Penacort Injection Each 100ml Contains: Prednisolone as Acetate (Sterile and Micronized)….0.750gm Dexamethasone (as Sodium Phosphate)…0.250gm	22-07-2003	Dy. No. 25143 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023
431.	29666	Oxy-TD Injection Each 100ml Contains: Oxytetyracycline…15gm Tripelenamine HCl…1gm Dexamethasone…0.05gm	22-07-2003	Dy. No. 25143 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023
432.	29663	Aminox Injection Each 100ml Contains: Novaminsulfon…4gm Etilefrin…0.02gm Calcium Gluconate…10gm Magnesium Gluconate…1gm Sodium Salicylate…0.7gm Nicotinamide…0.03gm Caffeine…1gm Boric Acid…1gm	22-07-2003	Dy. No. 25142 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023
433.	29664	Venazine Injection Each ml Contains: Sodium as Iodide…50mg Potassium as Iodide…50mg Potassium as Chloride…4.282mg Zinc as Chloride…0.135mg Manganese as Chloride…0.885mg Magnesium as Chloride…19.640mg Copper as Chloride…0.220mg Ferous as Chloride…12.960mg Molybdenum as Ammonium Molybdate…0.018mg Cobalt as Chloride...0.164mg Calcium as Gluconate...300mg	22-07-2003 Change of brand name dated: 15-10-2009	Dy. No. 25142 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023
434.	29661	Scour-X Oral Suspension Each 100ml Contains: Sulphadiazine…3.550gm Sulphadimidine…2.840gm Neomycin Sulphate…0.180gm Hyoscine Methylbromide…0.004gm Pectin…0.710gm Kaolin…10.330gm Vitamin B1…0.015gm Vitamin B2…0.022gm	22-07-2003	Dy. No. 25141 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023

435.	29662	Tono-10 Solution Each 100ml Contains: Toldimfos Sodium…10gm	22-07-2003 Change of brand name dated: 09-07-2005	Dy. No. 25141 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023
436.	49515	Hi-Resp Powder Each kg Contains: Tylosin Tartrate…100gm Doxycycline HCl…200gm Colistin Sulphate…500MIU Phenylbutazone…12gm Bromhexine…5gm	22-07-2008	Dy. No. 25140 dated 19-07-2018 10000/-	21-07-2023	w.e.f. 22-07-2018 to 21-07-2023
M/s. Univet Pharmaceuticals, 14-Km Adyala Road, Post Office Dahgal, Rawalpindi						
437.	021423	Enflox Powder Each gm Contains: Enrofloxacin…250mg	04-09-1998	Dy. No. 22791 dated 02-07-2018 10000/-		Deferred for status of License for Licensing Division.

iii. Imported Human (Reference)

Sr. No	Reg. No.	Manufacturer	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Roche Pakistan Ltd, 37-C, Block-6, P.E.C.H.S., Karachi							
438.	47663	Product License Holder: M/s Roche Pharma (Schweiz) AG Schonmattstrasse 2 Ch-4153 Reinach BL Switzerland Manufacturer: Vetter Pharma-Fertigung GmbH & Co., KG Eisenbahnstrasse 2-4 D-88085 Langenargen Germany.	Bonviva solution for injection in a Pre-filled syringe. Each pre-filled syringe contains: 3.375mg of Ibandronic acid monosodium salt, monohydrate (equivalent to 3mg Ibandronic acid	02-08-2008	Dy. No. 23220 dated 05-07-2018 20000/-	01-08-2023	w.e.f. 02-08-2018 to 01-08-2023 as per Import Policy for Finished Drugs.
M/s. Abbott Laboratories (Pakistan) Ltd, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi							
439.	047677	M/s Abbott Arzeimittel GmbH Freundalle 9A 30173 Hannover Germany Manufactured by: M/s Abbott Laboratories GmbH, Justus –Von –Liebig, Str,33,31535 Neustadt., Germany	Kreon 10000 Capsule Each Capsule Contains: Pancreatin 150mg in Enteric-Coated Granules minimicrosheres, eq. to 8,000 ph.Eur. Units Amylase 600 Ph.Eur. Units total Protease 10,000 Ph.Eur. Units Lipase	05-08-2008 Transfer of registration dated: 24-8-2011 Change in manufacturing site: 29-1-2014	Dy. No. 24372 dated 13-07-2018 20000/- CoPP No: 106/18 dated: 09-03-2018		Referred to Division of Biological Evaluation & Research as the source of API is biological.

iv. Imported Human (Non- Reference Countries)

Sr. No	Reg. No.	Manufacturer	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Pharmevo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi							
440.	047651	M/s Jiangsu Aosaikang Pharmaceutical Co., Limited, 699 , Kejian Road, Jiangning Science Park, Nanging PR China.	ONCOTAXEL 30 MG INJECTIONS. Each Vial Contains: PACLITAXEL ….. 30MG. (ANTI-CANCER).	09-07-2008	Dy. No. 23227dated 08-07-2018 20000/-		Deferred for evaluation as per Import Policy for Finished Drugs
441.	047652	-do-	OXALITIN 50 MG INJECTIONS. Each Vial Contains: OXALIPLATIN … 50MG. (ANTI-CANCER).	09-07-2008	Dy. No. 23227 dated 08-07-2018 20000/-		Deferred for evaluation as per Import Policy for Finished Drugs
442.	047653	-do-	OXALITIN 100MG INJECTION. Each Vial Contains: OXALIPLATIN …100MG. (ANTI-CANCER).	09-07-2008	Dy. No. 23227 dated 08-07-2018 20000/-		Deferred for evaluation as per Import Policy for Finished Drugs
M/s. Biocare Pharmaceutica, 807 Shadman-1, Lahore							
443.	028469	M/s Suzhou Dawnrays Pharmaceuticals Co., Ltd, No.22 Tianling Road, Wuzhongu Economic Development District Suzhou, Giangsu, China	Sulzone 2.0Gm Injection. Each Vial Contains: Cefoperazone as sodium salt 1.0gm. Sulbactam as sodium salt 1.0gm	06-08-2003	Dy. No. 25892 dated 27-07-2018 20000/-		Deferred for following: 1. Deferred for evaluation as per Import Policy for Finished Drugs. 2. Address of DSL varies from address on registration letter. 3. Clarification required because the clearance of the consignments was obtained from DRAP Karachi on the address M/s Biocare Pharmaceutica 705, Progressive Square , Block 6-PECHS Karachi whereas the registration holder is M/s. Biocare Pharmaceutica, 807 Shadman-1, Lahore 4.

							Legalized FSC submitted by the firm was expired on 30-3-2019, however valid at time of submission.
444.	028468	-do-	Sulzone 1.0Gm Injection Each Vial Contains: Cefoperazone as sodium salt 500mg. Sulbactam as sodium salt 500mg	06-08-2003	Dy. No. 25888 dated 27-07-2018 20000/-		Deferred for following: 1. Deferred for evaluation as per Import Policy for Finished Drugs. 2. Address of DSL varies from address on registration letter. 3. Clarification required because the clearance of the consignments was obtained from DRAP Karachi on the address M/s Biocare Pharmaceutica 705, Progressive Square , Block 6-PECHS Karachi whereas the registration holder is M/s. Biocare Pharmaceutica, 807 Shadman-1, Lahore 4. Legalized FSC submitted by the firm was expired on 30-3-2019, however valid at time of submission.
M/s. Getz Pharma (Pvt) Ltd, 29-30/27, Korangi Industrial Area, Karachi							
445.	072591	M/s Jewim Pharmaceuticals (Shandong Co. Limited), Middle of Chuangye Street, Taian Hi-Tech Industrial Developmental Zone Shandong Province China.	Bekson Forte HFA Inhaler 250mcg Each Metered Dose Contains: Beclomethasone Dipropionate…250mcg	05-09-2013	Dy. No. 24158 dated 12-07-2018 20000/-		Deferred for evaluation as per Import Policy for Finished Drugs
446.	072590	-do-	Bekson HFA Inhaler 50mcg Each Metered Dose Contains:	05-09-2013	Dy. No. 24157 dated 12-07-2018 20000/-		Deferred for evaluation as per Import Policy for Finished Drugs

			Beclomethasone Dipropionate…50mcg				
447.	72592	-do-	Xaltide HFA Inhaler 100mcg/50mcg Each Metered Dose Contains: Salbutamol (as Sulphate)…100mcg Beclomethasone Dipropionate…50mcg	05-09-2013	Dy. No. 24152 dated 12-07-2018 20000/-		Deferred for evaluation as per Import Policy for Finished Drugs

INCOMPLETE CASES

i. Local Manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Dy. No. Date of application (R&I) Fee submitted	Renewal validity	Remarks (if any)
M/s. Tagma Pharma (Pvt) Ltd, 12.5 Km Raiwind Road, Lahore						
448.	049964	Reetag Tablet Each Tablet Contains: Desloratadine…5mg	18-07-2008	Dy. No. 24315 12-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-2-2019 and 26-3-2019 which has not yet been responded by the firm.
449.	049965	Shic-5 Tablet Each Film Coated Tablet Contains: Levocetirizine…5mg	18-07-2008	Dy. No. 24315 12-07-2018 10000/-		-do-
450.	049966	Safotil 250mg Tablet Each Tablet Contains: Cefuroxime (Axetil)…250mg	18-07-2008	Dy. No. 24315 12-07-2018 10000/-		-do-
451.	049967	Co-Losartin Tablet Each Tablet Contains: Losartan Potassium…50mg Hydrochlorothiazide…12.5 mg	18-07-2008	Dy. No. 24315 12-07-2018 10000/-		-do-
452.	049968	Lexicap Dry Suspension Each 5ml Contains: Cephalexin…125mg	18-07-2008	Dy. No. 24315 12-07-2018 10000/-		-do-
453.	049969	Tagalox Dry Suspension Each 5ml Contains: Cefpodoxime as Proxetil…40mg	18-07-2008	Dy. No. 24315 12-07-2018 10000/-		-do-
454.	050934	T-Xium Capsule Each Capsule Contains: Esomeprazole as Magnesium Enteric Coated Pellets…40mg **Source:** M/s Lee Pharma (P) Limited, Flat No. 401-A, Saidatta Apartments	05-08-2008	Dy. No. 24315 12-07-2018 10000/-		-do-

		Srinivasa Nagar Colony East Hyderabad India.				
455.	051163	Tagalox Tablet Each Tablet Contains: Cefpodoxime as Proxetil…100mg	01-09-2008	Dy. No. 24315 12-07-2018 10000/-		-do-
456.	022102	Tagasone Tablet Each Tablet Contains: Dexamethasone…0.5mg	11-07-1998	Dy. No. 23684 dated 09-07-2018 10000/-		-do-
M/s. Farm Aid Group Pakistan, Plot 3/2, Phase 1/2, Industrial Estate, Hattar						
457.	051034	Aidocin Tablets 200mg. Each Tablet contains: Ofloxacin…… …200mg.	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-2-2019 which has not yet been responded by the firm.
458.	051035	Aidocin Tablets 400mg. Each Tablet contains: Ofloxacin…… …400mg.	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
459.	051036	Zirow Tablets 250mg. Each Tablet contains: Azithromycin…….250 mg.	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
460.	051038	Calfa Tablets 250mg. Each Tablet contains: Clarithromycin……..250 mg.	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
461.	051039	Calfa Tablets 500mg. Each Tablet contains: Clarithromycin ……..500mg. (USP Specs)	13-08-2008	Dy. No. 26212 dated 31-07-2018 10000/-		-do-
462.	051040	Esofarm 20mg Tablet Each Tablet contains: Esomeprazole (as magnesium trihydrate) ….. 20mg	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
463.	051041	Esofarm 40mg Tablet Each Tablet contains: Esomeprazole (as magnesium trihydrate) …… 40mg	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
464.	051042	Arlum Tablets. Each Tablet Contains: Artemether…….20mg Lumefantrine…… 120mg.	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
465.	051043	Piproxcin Tablets 250mg. Each Tablet contains: Ciprofloxacin as	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-

		HCl……250mg. (B.P Specs)				
466.	051044	Piproxcin Tablets 500mg. Each Tablet contains: Ciprofloxacin as HCl……500mg. (B.P Specs)	13-08-2008	Dy. No. 26212 31-07-2018 10000/-		-do-
467.	29668	Emericid Powder Each 1000gm Contains: Diaveridin…50gm Sulphaquinoxaline…200gm Vitamin A…2.5MIU Vitamin K3…5.0gm Vitamin E…1.0gm Sodium Citrate…50gm Sodium Carbonate…250gm	28-07-2003	Dy. No. 22998 03-07-2018 10000/-		-do-
468.	29669	Neomycin-72 Water Soluble Powder Each Kg Contains: Neomycin Sulphate…720gm	28-07-2003	Dy. No. 22998 03-07-2018 10000/-		-do-
469.	29670	Albenda Plus Suspension Contains: Albendazole…2.5%w/v Cobalt Chloride…0.075%w/v Sodium Selenite…0.035%w/v	28-07-2003	Dy. No. 22998 03-07-2018 10000/-		-do-
470.	31434	Tylo-Cycline 450 Powder Each gm Contains: Tylosin Tartrate…200mg Doxycycline HCl…250mg	04-10-2003	Dy. No. 22998 03-07-2018 10000/-		-do-
471.	31435	Farbendol 2.5 Suspension Each 100ml Contains: Albendazole…2.5gm Closantel…0.5gm	04-10-2003	Dy. No. 22998 03-07-2018 10000/-		-do-
M/s. Pakistan Pharmaceutical Products (Pvt) Ltd, D-122, S.I.T.E., Karachi						
472.	014278	Cepadin Injection 250mg Each Vial Contains: Cephradine Sterile…250mg	05-08-1993	Dy. No. 26224 31-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-2-2019 which has not yet been responded by the firm.
473.	014279	Cepadin Injection 500mg Each Vial Contains: Cephradine Sterile…500mg	05-08-1993	Dy. No. 26224 31-07-2018 20000/-		-do-
474.	014280	Cepadin Injection 1gm Each Vial Contains: Cephradine Sterile…1gm	05-08-1993	Dy. No. 26224 31-07-2018 20000/-		
475.	014281	Ulcedine Injection 200mg Each 2ml Contains: Cimetidine….200mg	05-08-1993	Dy. No. 26224 31-07-2018 10000/-		
476.	073667	Pemose 20mg Capsule	07-01-2013	Dy. No. 22813		

			08-07-2013 Change	02-07-2018 20000/-		
477.	073668	Pemose 40mg Capsule	07-01-2013 08-07-2013 Change	Dy. No. 22813 02-07-2018 20000/-		
478.	006792	Savimycin 100mg Capsule	13-08-1984 10-07-2003 Change	Dy. No. 22813 02-07-2018 10000/-		
ii.	**M/s. Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km Ferozepur Road, Lahore**					
479.	030260	Dosium Capsules 50mg Each capsule contains: Diclofenac Potassium ..50mg	31-07-2003	Dy. No. 26022 30-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-2-2019, which has not yet been responded by the firm.
480.	030258	Dross Capsule Each capsule contains: Doxycycline (s Hyclate)..100mg	28-07-2003	Dy. No. 25821 26-07-2018 10000/-		-do-
481.	030259	Riboprofen Tablets 100mg Each tablet contains: Flurbiprofen …….100mg	28-07-2003	Dy. No. 25821 26-07-2018 10000/-		-do-
482.	051199	Cefimax Dry Suspension Each 5ml contains: Cefixime……..100m g (USP Specs)	11-09-2008	Dy. No. 25820 26-07-2018 10000/-		-do-
483.	051200	Azimax-250 Tablets Each film coated tablet contains: Azithromycin……..250 mg	11-09-2008	Dy. No. 25820 26-07-2018 10000/-		-do-
484.	49820	Maxvit Tablet 0.5mcg Each Film Coated Tablet Contains: Alfacalcido1…0.5mcg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
485.	49821	Mecbin Tablet 500mcg Each Tablet Contains: Mecobalamin…500mcg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
486.	49822	Iromax Tablet Each Film Coated Tablet Contains: Iron Polymaltose Complex…100mg Folic Acid…0.35mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
487.	49825	Glucolox Tablet Each Film Coated Tablet Contains: Glucosamine Sulfate…500mg Chondroitin Sulfate Sodium…400mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
488.	49827	Citofer 10mg Tablet Each Film Coated Tablet Contains:	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-

		Citalopram…10mg				
489.	49828	Citofer 20mg Tablet Each Film Coated Tablet Contains: Citalopram…20mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
490.	49838	O-Max Tablet 200mg Each Tablet Contains: Ofloxacin…200mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
491.	49840	Gabocap 100mg Capsule Each Capsule Contains: Gabapentin…100mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
492.	49841	Gabocap 300mg Capsule Each Capsule Contains: Gabapentin…300mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
493.	49842	Gabocap 400mg Capsule Each Capsule Contains: Gabapentin…400mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
494.	49843	Malan Capsule 120/20mg Each Capsule Contains: Artemether…20mg Lumefantrine…120mg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
495.	49844	Mecap Capsule 500mcg Each Capsule Contains: Mecobalamin…500mcg	16-07-2008	Dy. No. 24189 12-07-2018 10000/-		-do-
496.	49918	Cefimax Dry Suspension 200mg Each 5ml Contains: Cefixime…200mg	17-07-2008	Dy. No. 24188 12-07-2018 10000/-		-do-
497.	49919	Cefimax 400mg Capsule Each Capsule Contains: Cefixime…400mg	17-07-2008	Dy. No. 24188 12-07-2018 10000/-		-do-
498.	49823	Diclomax Tablet 75mg Each Enteric Coated Tablet Contains: Diclofenac Sodium…75mg	16-07-2008	Dy. No. 24188 12-07-2018 10000/-		-do-
499.	49824	Ferother Tablet 120/20mg Each Film Coated Tablet Contains: Artemether…20mg Lumefantrine…120mg	16-07-2008	Dy. No. 24188 12-07-2018 10000/-		-do-
500.	30254	Melow 7.5mg Tablets Each tablet contains: Meloxicam …… 7.5mg	31-07-2003	Dy. No. 25925 27-07-2018 10000/-		-do-
501.	30255	Melow 15mg Tablets Each tablet contains: Meloxicam …… 15mg	31-07-2003	Dy. No. 25925 27-07-2018 10000/-		-do-
502.	30256	Lexical Capsules Each capsule contains: Lansoprazole ……..30mg	31-07-2003	Dy. No. 25925 27-07-2018 10000/-		-do-
M/s. Pharmedic Laboratories (Pvt) Ltd, 16-Km Multan Road, Lahore						
503.	028663	Virazide-400 Tablet Each Tablet Contains: Ribavirin…400mg	26-08-2003	Dy. No. 26307 31-07-2018 10000/-		Panel Inspection report dated 7-8-2018, 4-9-2018 & 22-11-2018 concludes that Firm was advised to rectify

						observations made during GMP inspection & submit compliance report
504.	014294	Zynol-300 Tablet Each Tablet Contains: Allopurinol…300mg	05-08-1993	Dy. No. 26308 31-07-2018 10000/-		-do-
505.	50090	Malasunate Tablets (combo Pack) 100mg. Each combo Pack: 1st Tablet contains:- Artesunate……. .100mg & 2nd Tablet contains:- Pyrimethamine……2 5mg. Sulfadoxine…… …500mg	23-07-2008	Dy. No. 24026 11-07-2018 10000/-		-do-
M/s. MBL Pharma, Plot No. B-77/A, Hub Industrial Trading Estate, Baluchistan						
506.	050384	MB Stine Tablet 10mg Each Tablet Contains: Ebastine…10mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		Evidence of submission of last renewal (2013) is not submitted by firm.
507.	050385	MB Cobal Tablet 500mcg Each Tablet Contains: Mecobalamin…500mcg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
508.	050386	MB Cobal Injection 500mcg Each 1ml Contains: Mecobalamin…500mcg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
509.	050387	Anbox Capsule 10mg Each Capsule Contains: Piroxicam…10mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
510.	050388	Anbox Capsule 20mg Each Capsule Contains: Piroxicam…20mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
511.	050389	Anbox 0.5% Gel Each gm Contains: Piroxicam…5mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
512.	050390	Xaser Tablet 10mg Each Tablet Contains: Cetirizine Dihydrochloride…10mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
513.	050391	Xaser 1mg/ml Syrup Each ml Contains: Cetirizine Dihydrochloride…1mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-		-do-
M/s. Alson Pharmaceutical, Plot No. 169, Road No. 7-B, Industrial Estate Hayatabad, Peshawar						
514.	050830	Nefcol Tablet 200mg Each Tablet Contains: Ofloxacin…200mg	30-07-08	Dy. No. 26191 30-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 26-2-2019, which has not yet been responded by

						the firm.
515.	050831	Salmonil Tablet 500mg Each Tablet Contains: Levofloxacin…500mg	30-07-08	Dy. No. 26192 30-07-2018 10000/-		-do-
516.	050832	Salmonil Tablet 250mg Each Tablet Contains: Levofloxacin…250mg	30-07-08	Dy. No. 26186 30-07-2018 10000/-		-do-
517.	050833	Neget Tablet 500mg Each Tablet Contains: Ciprofloxacin as HCl…500mg	30-07-08	Dy. No. 26189 30-07-2018 10000/-		-do-
518.	050834	Neget Tablet 250mg Each Tablet Contains: Ciprofloxacin as HCl…250mg	30-07-08	Dy. No. 26187 30-07-2018 10000/-		-do-
519.	050835	Dolaf Tablet Each Tablet Contains: Alfacalcidol…0.5mcg	30-07-08	Dy. No. 26190 30-07-2018 10000/-		-do-
520.	050836	Ansol Tablet Each Tablet Contains: Escitalopram as Oxalate…10mg	30-07-08	Dy. No. 26188 30-07-2018 10000/-		-do-
M/s Batala Pharmaceuticals, 23/B, Small Industrial Estate No. 2, Near Wapda Town, Khiali Bye-Pass, Gujranwala.						
521.	031128	Beflam Tablets 75mg Each tablet contains: Diclofenac Potassium ….75mg	30-09-2003	Dy. No. 25511 23-07-2018 10000/-		Inspection report of 2015 is submitted.
M/s Synchro Pharmaceuticals, 77-Industrial Estate, KotLakhpat, Lahore						
522.	050842	Trucef Injection 1500mg. Each Vial Contains: Cefuroxime…1500mg	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 26-2-2019, which has not yet been responded by the firm.
523.	050843	Ceftisyn Injection. Each Vial Contains: Ceftizoxime…500mg	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		-do-
524.	050844	Synolin Injection 250mg. Each Vial Contains: Cefazoline…250mg	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		-do-
525.	050845	Synolin Injection 500mg. Each Vial Contains: Cefazoline…500mg	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		-do-
526.	050846	Synolin Injection 1000mg. Each Vial Contains: Cefazoline…1000mg	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		-do-
527.	050847	Taxocyn Injection 2000mg. Each Vial Contains: Ceftriaxone……..20 00mg. (USP Specs)	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		-do-
528.	050848	Oxicef Capsules. Each Capsule Contains: Cefadroxil as Monohydrate	30-07-2008	Dy. No. 25529 23-07-2018 10000/-		-do-

		USP……...…..500mg (USP)				
M/s. Wilson's Pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad						
529.	030922	Herr-C 1000 Tablet (Effervescent) Each tablet contains: Calcium Carbonate.....550mg Calcium Lactate Gluconate..250mg Vitamin C.....500mg Folic Acid.....1mg Vitamin B12.....250mcg	28-07-2003	Dy. No. 25530 23-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 28-2-2019, which has not yet been responded by the firm.
530.	030923	Strength Sachets Each sachet contains: Calcium Glycerophosphate…..400mg Vitamin C.....150mg Thiamine.....5mg Pyridoxine.....5mg Riboflavin……...5mg Nicotinamide.....15mg	28-07-2003	Dy. No. 25530 23-07-2018 10000/-		-do-
531.	014237	Epirate Tablet Each Tablet Contains: Sodium Valporate…200mg	05-08-1993	Dy. No. 25530 23-07-2018 10000/-		-do-
532.	014240	Normacid Suspension Each 5ml Contains: Cimetidine…100mg	05-08-1993	Dy. No. 25530 23-07-2018 10000/-		-do-
533.	014239	Normacid Tablet Each Tablet Contains: Cimetidine…400mg	05-08-1993	Dy. No. 25530 23-07-2018 10000/-		-do-
534.	014241	Scabiderm Cream Contains: Permethrin…5%w/w	05-08-1993	Dy. No. 25530 23-07-2018 10000/-		-do-
535.	031083	Gem-SR Tablet Each tablet contains: Pantoprazole (as Sodium Sesquihydrate)……40mg	05-10-2003	Dy. No. 25530 23-07-2018 10000/-		-do-
536.	031082	Reset-SR Tablet Each tablet contains: Lansoprazole…….30mg	05-10-2003	Dy. No. 25530 23-07-2018 10000/-		-do-
537.	010011	Duodopa Forte Tablet Each tablet contains: CARBIDOPA 25MG LEVODOPA 250MG	31-10-1988	Dy. No. 25530 23-07-2018 10000/-		-do-
538.	010021	CALCEE-500 SACHETS Each sachet contains: CALCIUM LACTATE GLUCONATE 1000MG (CALCIUM GLUCONATE 578MG, CALCIUM LACTATE 422MG) VITAMIN C 500MG CALCIUM CARBONATE	29-11-1988	Dy. No. 25530 dated 23-07-2018 10000/-		-do-

		327MG				
539.	010029	Slepam Capsule 15mg Each tablet contains: EnalaprilTenazepam.....15mg	29-11-1988	Dy. No. 25530 23-07-2018 10000/-		-do-
540.	022555	A2A Tablet 25mg Each Tablet Contains: Losartan Potassium…25mg	26-11-1998	Dy. No. 25530 23-07-2018 10000/-		-do-
541.	022556	A2A Tablet 50mg Each Tablet Contains: Losartan Potassium…50mg	26-11-1998	Dy. No. 25530 23-07-2018 10000/-		-do-
542.	022593	Promethazine Syrup Each 5ml Contains: Promethazine HCl…25mg	14-12-1998	Dy. No. 25530 23-07-2018 10000/-		-do-
543.	022590	Talergin-F Capsule Each Capsule contains: Fexofenadine as Hcl.60mg	14-12-1998	Dy. No. 25530 23-07-2018 10000/-		-do-
544.	054800	Season Sachet 4mg Each sachet contains: Montelukast Sodium equivalent to Montelukast……4mg	31-12-2008	Dy. No. 25530 23-07-2018 10000/-		-do-
545.	053799	Teli-H Tablets Each tablet contains: Telmisartan……..80 mg Hydrochlorothiazide……25 mg	31-12-2008	Dy. No. 25530 23-07-2018 10000/-		-do-
M/s Pfizer Pakistan Ltd, B-2, S.I.T.E., Karachi						
546.	075986	Antmal Suspension Each 5ml contains: Artemether……15mg Lumefantrine…90 mg	22-07-2013	Dy. No. 25512 23-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 1-3-2019 and 08-04-2019 which has not yet been responded by the firm.
547.	075971	Celebrex 100mg Capsule Each Capsule Contains: Celecoxib…100mg	04-07-2013	Dy. No. 23004 03-07-2018 10000/-		-do-
548.	075972	Celebrex 200mg Capsule Each Capsule Contains: Celecoxib…200mg	04-07-2013	Dy. No. 23004 03-07-2018 10000/-		-do-
M/s Tabros Pharma (Pvt) Ltd, L-20/B, Sector-22, F.B. Industrial Area, Karachi						
549.	014343	Hemsamic Capsule 250mg Each Capsule Contains: Tranexamic Acid…250mg	14-10-1993	Dy. No. 25525 23-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 1-3-2019 which has not yet been responded by the firm.
550.	014344	Hemsamic Capsule	14-10-1993	Dy. No. 25525		-do-

		500mg Each Capsule Contains: Tranexamic Acid…500mg		23-07-2018 10000/-		
551.	014345	Hemsamic Injection 250mg/5ml Each 5ml Contains: Tranexamic Acid…250mg	14-10-1993	Dy. No. 25525 23-07-2018 10000/-		-do-
M/s. Safe Pharmaceuticals (Pvt) Ltd, Plot No. C-I-20, Sector 6-B, North Karachi Industrial Area, Karachi						
552.	048847	Planex-DS 200mg/5ml Dry Suspension Each 5ml Contains: Cefixime…200mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 1-3-2019 which has not yet been responded by the firm.
553.	048848	Sluber 100mg Tablet Each Tablet Contains: Flurbiprofen…100mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
554.	048849	Ocebid 400mg Tablet Each Tablet Contains: Ofloxacin…400mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
555.	048850	Ocebid 200mg/100ml Infusion Each 100ml Contains: Ofloxacin…200mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
556.	048851	Saferozil 125mg/5ml Suspension Each 5ml Suspension Contains: Cefprozil…125mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
557.	048852	Saferozil 250mg/5ml Suspension Each 5ml Suspension Contains: Cefprozil…250mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
558.	048853	Safedinir 50mg/5ml Suspension Each 5ml Suspension Contains: Cefdinir…50mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
559.	048854	Safedinir 100mg Capsule Each Capsule Contains: Cefdinir…100mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
560.	048855	Safedroxil 500mg Capsule Each Capsule Contains: Cefadroxil (as Monohydrate)…500mg	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
561.	048856	Safedroxil 1gm Capsule Each Capsule Contains: Cefadroxil (as Monohydrate)…1gm	24-07-2008	Dy. No. 24775 17-07-2018 10000/-		-do-
562.	048857	Voltec 75mg Tablet	24-07-2008	Dy. No. 24776		-do-

		Each Tablet Contains: Diclofenac Sodium…75mg		17-07-2018 10000/-		
563.	048858	Voltec SR 100mg Tablet Each Sustained Release Tablet Contains: Diclofenac Sodium…100mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
564.	048859	Safelexin 125mg/5ml Suspension Each 5ml Contains: Cephalexin…125mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
565.	048860	Safelexin 250mg/5ml Suspension Each 5ml Contains: Cephalexin…250mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
566.	048861	Safelexin 250mg Capsule Each Capsule Contains: Cephalexin…250mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
567.	048862	Safelexin 500mg Capsule Each Capsule Contains: Cephalexin…500mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
568.	048863	Orpic 250mg Tablet Each Tablet Contains : Ciprofloxacin (as HCl)…250mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
569.	048864	Orpic 500mg Tablet Each Tablet Contains : Ciprofloxacin (as HCl)…500mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
570.	048865	Orpic 750mg Tablet Each Tablet Contains : Ciprofloxacin (as HCl)…750mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
571.	048866	Orpic 200mg/100ml Infusion Each 100ml Contains: Ciprofloxacin (as HCl)…200mg	24-07-2008	Dy. No. 24776 17-07-2018 10000/-		-do-
572.	048867	Safeclor 125mg/5ml Suspension Each 5ml Suspension Contains: Cefaclor (as Monohydrate)…125mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
573.	048868	Safeclor 250mg/5ml Suspension Each 5ml Suspension Contains: Cefaclor (as Monohydrate)…250mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
574.	048869	Safeclor 250mg Capsule Each Capsule Contains: Cefaclor (as Monohydrate)…250mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
575.	048870	Safeclor 500mg Capsule	24-07-2008	Dy. No. 24777		-do-

		Each Capsule Contains: Cefaclor (as Monohydrate)…500mg		17-07-2018 10000/-		
576.	048871	Saferoxime 125mg/5ml Suspension Each 5ml Contains: Cefuroxime (as Axetil)…125mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
577.	048872	Saferoxime 250mg Injection Each Vial Contains: Cefuroxime (as Sodium)…250mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
578.	048873	Saferoxime 750mg Injection Each Vial Contains: Cefuroxime (as Sodium)…750mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
579.	048874	Saferoxime 1.5g Infusion Each Vial Contains: Cefuroxime (as Sodium)…1.5gm	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
580.	048875	Safepime 500mg Infusion Each Vial Contains: Cefepime (as HCl)…500mg	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
581.	048876	Safepime 1g Infusion Each Vial Contains: Cefepime (as HCl)…1gm	24-07-2008	Dy. No. 24777 17-07-2018 10000/-		-do-
M/s. Spectrum Laboratories (Pvt) Ltd, 8 Km Raiwind Road, Lahore						
582.	008399	Wormonil Syrup Each 5ml Contains: Piperazine (as Piperazine Hydrate)…750mg	27-06-1985 Transfer of registration dated: 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.
583.	008400	Amenol Cough Syrup Each 5ml Contains: Ammonium Chloride…100mg Sodium Citrate…60mg Ephedrine HCl…7mg Chlorpheniramine…… 2mg Maleate Menthol…..1mg	27-06-1985 Transfer of registration dated: 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
584.	008243	Tincture Iodine Methyl USP Contains: Iodine…2% Sodium Iodine…2.5% Methylated Spirit…50% Aqua…100%	12-05-1985 Transfer of registration dated: 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
585.	008245	Tincture Benzoin Co USP Contains:	12-05-1985	Dy. No. 24374 13-07-2018		-do-

		Rosin…8% Benzoin…10% Aloes…2% Balsum Tolu…4% Methylated Spirit…100%	Transfer of registration dated: 15-11-1988	10000/-		
586.	009495	Phenrol Tablet Each Tablet Contains: Chlorpheniramine Maleate…4mg	08-12-1986 Transfer of registration dated: 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
587.	009494	Sodalk Syrup Each 5ml Contains: Sodium Acid Citrate…1.25g	08-12-1986 Transfer of registration dated: 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
588.	008244	Ichthammol Glycerin BPC Contains: Ichthammol…10% Glycerin…100%	12-05-1985 Transfer of registration dated: 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
589.	008808	Sodamint Tablet Each Tablet Contains: Sodium Bicarbonate…300mg	12-02-1986 Transfer of registration dated : 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
590.	008401	Poultis Contains: Kaoline Heavy…52.7g Boric Acid…4.5g Methyl Salicylate…0.2ml Peppermint Oil…0.05ml Thymol…0.05ml Glycerin…42.50g	27-06-1985 Transfer of registration dated : 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
591.	009502	Nilacid Mixture Contains: Sodium Bicarbonate…5% Spirit Ammonia Aromatic…6.5% Tincture Zinger Fort…0.4% Tincture Card Co…6.5% Spirit Chloroform…4% Aqua Mentha Pip. Conc…4.8%	09-12-1986 Transfer of registration dated : 15-11-1988	Dy. No. 24374 dated 13-07-2018 10000/-		-do-
592.	009501	Aspodil Tablet Each Tablet Contains: Aspirin…300mg	09-12-1986 Transfer of registration dated : 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
593.	009713	Hydrogen Peroxide 20 Vol.	17-03-1988 Transfer of registration dated : 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
594.	008398	Bevit Syrup Each 15ml Contains:	27-06-1985 Transfer of	Dy. No. 24374 13-07-2018		-do-

		Thiamine HCl…3.0mg Riboflavine…3.0mg Pyridoxine HCl…2.0mg	registration dated : 15-11-1988	10000/-		
595.	008397	Caltol Syrup Each 5ml Contains: Paracetamol…120mg	27-06-1985 Transfer of registration dated : 15-11-1988	Dy. No. 24374 13-07-2018 10000/-		-do-
596.	014714	Amenol-D Cough Syrup Each 5ml Contains: Dextromethorphan Hbr…10mg Ephedrine HCl…7mg Chlorpheniramine Maleate…2mg	24-11-1993	Dy. No. 24374 13-07-2018 10000/-		-do-
M/s. ATCO Laboratories Ltd., B-18, S.I.T.E., Karachi						
597.	50519	Trimalor Adult Tablet Each co-blister contains: Each six small tablets contains:- Artesunate……...100mg Each three large tablets contains:- Sulfadoxine……500mg Pyrimethamine……25mg	29-08-2008	Dy. No. 25929 27-07-2018 10000/-		Firm was asked to provide the details regarding the manufacturing facility of co-blistering, but they didn't respond.
M/s. Raazee Therapeutics (Pvt) Ltd, 48 Km, Lahore-Kasur Road, Kasur.						
598.	21843	Cestonil Plus Syrup Each 5ml Contains: Pizotifen as Hydrogen Malate…0.250mg Thiamine HCl…0.875mg Riboflavin Phosphate…1.310mg Pyridoxine HCl…0.770mg Nicotinamide…5.250mg	31-08-1998	Dy. No. 25158 19-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.
599.	21844	Texcol Allergy Tablet 10mg Each Tablet Contains: Loratadin…10mg	31-08-1998 Change of brand name dated 31-1-2000	Dy. No. 25158 19-07-2018 10000/-		-do-
600.	30888	Tocor Forte Tablet Each Tablet Contains: Codeine Phosphate…15mg Paracetamol…500mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
601.	30889	Acabose Tablet 50mg Each Tablet Contains: Acarbose…50mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
602.	30890	Acabose Tablet 100mg Each Tablet Contains: Acarbose…100mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
603.	30891	Gewan Tablet 30mg Each Tablet Contains: Gliquidone…30mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
604.	30892	Ferogad Drops 50mg	17-09-2003	Dy. No. 25158		-do-

		Each ml Contains: Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron…50mg		19-07-2018 10000/-		
605.	30894	Reduse 10mg Tablet Each Tablet Contains: Atorvastatin (as Calcium Salt)…10mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
606.	30895	Reduse 20mg Tablet Each Tablet Contains: Atorvastatin (as Calcium Salt)…20mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
607.	30896	Texcol Bronco Syrup Each 5ml Contains: Acefylline Piperazine…125mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
608.	30897	Texcol EX Syrup Each 5ml Contains: Acefylline Piperazine…45mg Diphenhydramine HCl…8mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
609.	30898	Virol Tablet 600mg Each Film Coated Tablet Contains: Ribavirin…600mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
610.	30899	Reduse 40mg Tablet Each Tablet Contains: Atorvastatin (as Calcium Salt)…40mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
611.	30900	Mipine 30mg Tablet Each Tablet Contains: Mirtazapine…30mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
612.	30902	Calgesic SR 750mg Tablet Each Tablet Contains: Naproxen (as Sodium)…750mg	17-09-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
613.	31963	Tributine 100mg Tablet Each Tablet Contains: Trimebutine Maleate…100mg	11-12-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
614.	31964	Tributine Suspension Each- 100ml Contains: Trimebutine Maleate…0.48gm	11-12-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
615.	31965	Droverine 40mg Tablet Each Tablet Contains: Drotacerine HCl…40mg	11-12-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
616.	31966	Nysol Oral Solution Each 500ml Contains: Sodium Chloride…1.75gm Trisodium Citrate Dihydrate…1.45gm Potassium Chloride…0.75gm	11-12-2003	Dy. No. 25158 19-07-2018 10000/-		-do-

		Glucose Anhydrous…10.0gm				
617.	31967	Pethil Tablet 800mg Each Tablet Contains: Piracetam…800mg	11-12-2003	Dy. No. 25158 19-07-2018 10000/-		-do-
618.	53697	Xomal Plus DS Tablet Each Tablet Contains: Artemether…40mg Lumefantrine…240mg	06-12-2008	Dy. No. 25158 19-07-2018 10000/-		-do-
619.	53698	Lamx 500mcg Tablet Each Chewable Tablet Contains: Mecobalamin…500mcg	06-12-2008 Change of brand name dated: 18-5-2011	Dy. No. 25158 19-07-2018 10000/-		-do-
620.	53699	Melox 7.5mg Tablet Each Tablet Contains: Meloxicam…7.5mg	06-12-2008	Dy. No. 25158 19-07-2018 10000/-		-do-
621.	53700	Melox 15mg Tablet Each Tablet Contains: Meloxicam…15mg	06-12-2008	Dy. No. 25158 19-07-2018 10000/-		-do-
622.	53703	Ezevas 10/10mg Tablet Each Film Coated Tablet Contains: Ezetimibe…10mg Simvastatin…10mg	06-12-2008	Dy. No. 25158 19-07-2018 10000/-		-do-
623.	53704	Ezevas 10/20mg Tablet Each Film Coated Tablet Contains: Ezetimibe…10mg Simvastatin…20mg	06-12-2008	Dy. No. 25158 19-07-2018 10000/-		-do-
624.	53705	Gluchon Tablet Each Film Coated Tablet Contains: Glucosamine Sulphate…500mg Chondroitin Sulphate…400mg	06-12-2008	Dy. No. 25158 19-07-2018 10000/-		-do-
M/s. Shaigan Pharmaceuticals (Pvt) Ltd, 14 Km Adyala Road, Post Office Dahgal, Rawalpindi						
625.	051100	Pegalin-75 Capsule Each Capsule Contains: Pregabalin…75mg	20-08-2008	Dy. No. 22819 02-07-2018 10000/-		Approval of change of brand name is required.
626.	051104	Pegalin-150 Capsule Each Capsule Contains: Pregabalin…150mg	20-08-2008	Dy. No. 22819 02-07-2018 10000/-		-do-
627.	051102	Pegalin-300 Capsule Each Capsule Contains: Pregabalin…300mg	20-08-2008	Dy. No. 22819 02-07-2018 10000/-		-do-
M/s. Medisure Laboratories Pakistan (Pvt) Ltd, A-115, S.I.T.E. II, Super Highway, Karachi						
628.	050355	Quopine Tablet Each film coated tablet contains: Quetiapine (as Fumarate)……300mg	31-07-2008	Dy. No. 25024 dated 18-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.

629.	4184-EX	Rumapril Tablet 5mg Each Tablet Contains: Lisinopril Dihydrate eq. to Anhydrous Lisinopril…5mg	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
630.	4185-EX	Rumapril Tablet 10mg Each Tablet Contains: Lisinopril Dihydrate eq. to Anhydrous Lisinopril…10mg	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
631.	4186-EX	Gemxit Tablet 320mg Each Film Coated Tablet Contains: Gemifloxacin as Mesylate…….320mg.	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
632.	4187-EX	Rumagrel Tablet 75mg Each Tablet Contains: Clopidogrel…75mg	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
633.	4188-EX	Rumaflam Tablet 50mg Each Tablet Contains: Diclofenac Sodium…50mg	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
634.	4189-EX	Rumaflam Tablet 100mg Each Tablet Contains: Diclofenac Sodium…100mg	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
635.	4190-EX	Rumapine Tablet 10mg Each Tablet Contains: Amlodipine…10mg	02-07-2013	Dy. No. 25024 18-07-2018 10000/-		-do-
iii.	**M/s. Jawa Pharmaceuticals (Pvt) Ltd, 112/10 Quaid-e-Azam Industrial Area, Kot Lakhpat, Lahore**					
636.	050299	Ulcicare 20mg Capsule Each Capsule Contains: Esomeprazole as Enteric Coated Pellets eq. to…20mg M/s Smilex Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar Balanagar, Hyderabad India	29-07-2008	Dy. No. 25137 19-07-2018 10000/-		Differential fee for the year 2013 is also required. GMP is of 2017.
637.	050300	Ulcicare 40mg Capsule Each Capsule Contains: Esomeprazole as Enteric Coated Pellets eq. to…40mg M/s Smilex Laboratories Ltd., Plot No. 44 CIE Gandhi Nagar Balanagar, Hyderabad India	29-07-2008	Dy. No. 25137 19-07-2018 10000/-		-do-
638.	050801	Lecetzi 5mg Tablet Each Tablet Contains: Levocetirizine 2HCl…5mg	29-07-2008	Dy. No. 25137 19-07-2018 10000/-		-do-
639.	050802	Amacure 5mg Tablet Each Tablet Contains: Montelukast Sodium…5mg	29-07-2008	Dy. No. 25137 19-07-2018 10000/-		-do-
640.	050803	Amacure 10mg Tablet	29-07-2008	Dy. No. 25137		-do-

		Each Tablet Contains: Montelukast Sodium…10mg		19-07-2018 10000/-		
641.	050804	Joxicam 7.5mg Tablet Each Tablet Contains: Meloxicam…7.5mg	29-07-2008	Dy. No. 25137 19-07-2018 10000/-		-do-
642.	050805	Joxicam 15mg Tablet Each Tablet Contains: Meloxicam…15mg	29-07-2008	Dy. No. 25137 19-07-2018 10000/-		-do-
M/s. Neutro Pharma (Pvt) Ltd, 9.5 Km, Sheikhupura Road, Lahore						
643.	049427	Claromy Tablet 250mg Each Tablet Contains: Clarithromycin…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.
644.	049428	Azineu Tablet 250mg Each Tablet Contains: Azithromycin…250mg	15-07-2008 Change of brand name dated: 05-06-2013	Dy. No. 24174 12-07-2018 10000/-		-do-
645.	049429	Pefalo Tablet Each Film Coated Tablet Contains: Pefloxacin…400mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
646.	049430	Neumox Tablet 400mg Each Tablet Contains: Moxifloxacin…400mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
647.	049431	Lomef Tablet 200mg Each Tablet Contains: Lomefloxacin…200mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
648.	049432	Affif Tablet 250mg Each Tablet Contains: Ciprofloxacin as HCl…250mg	15-07-2008 Change of brand name dated: 05-06-2013	Dy. No. 24174 12-07-2018 10000/-		-do-
649.	049433	Affif Tablet 500mg Each Tablet Contains: Ciprofloxacin as HCl…500mg	15-07-2008 Change of brand name dated: 05-06-2013	Dy. No. 24174 12-07-2018 10000/-		-do-
650.	049434	Bacrid Tablet 200mg Each Tablet Contains: Ofloxacin…200mg	15-07-2008 Change of brand name dated: 18-10-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
651.	049435	Lefoxin Tablet 250mg Each Tablet Contains: Levofloxacin…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
652.	049436	Sparf Tablet 100mg Each Tablet Contains: Sparfloxacin…100mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
653.	049437	Numecomin Tablet Each Tablet Contains:	15-07-2008	Dy. No. 24174 12-07-2018		-do-

		Methylcobalamin…500mcg		10000/-		
654.	049438	Indrop Alpha Tablet Each Tablet Contains: Alfacalcidol…0.5mcg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
655.	049439	Muvon Tablet Each Film Coated Tablet Contains: Piroxicam as Beta-Cyclodextrin…20mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
656.	049440	Octina Tablet Each Film Coated Tablet Contains: Ranitidine as HCl…150mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
657.	049441	Levopri Tablet Each Film Coated Tablet Contains: Levosulpride…25mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
658.	049442	Otengel Tablet Each Tablet Contains: Naproxen Sodium…550mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
659.	049443	Inovel Tablet Each Tablet Contains: Artemether…20mg Lumefantrine…120mg	15-07-2008 Change of brand name dated: 22-04-2009	Dy. No. 24174 12-07-2018 10000/-		-do-
660.	049444	Nuwel Tablet 5mg Each Tablet Contains: Levocetirizine 2HCl…5mg	15-07-2008 Change of brand name dated: 05-06-2013	Dy. No. 24174 12-07-2018 10000/-		-do-
661.	049445	Neutrin Suspension Each 5ml Contains: Cefatrizine…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
662.	049446	Neudoxine Suspension Each 5ml Contains: Cefpodoxime as Proxetil…40mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
663.	049447	Actacef Capsule 250mg Each Capsule Contains: Cefadroxil…250mg	15-07-2008 Change of brand name dated: 27-3-2009	Dy. No. 24174 12-07-2018 10000/-		-do-
664.	049448	Actacef Capsule 500mg Each Capsule Contains: Cefadroxil as Monohydrate…500mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
665.	049449	Tefra Capsule 250mg Each Capsule Contains: Cefradine…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
666.	049450	Neulexin Capsule Each Capsule Contains: Cephalexin as Monohydrate…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
667.	049451	Serve Capsule 400mg Each Capsule Contains: Cefixime…400mg	15-07-2008 Change of brand name:	Dy. No. 24174 12-07-2018 10000/-		-do-

			22-04-2009			
668.	049452	Neutrocolor Capsule 250mg Each Capsule Contains: Cefaclor…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
669.	049453	Neuprozil Capsule Each Capsule Contains: Cefprozil…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
670.	049454	Neutrocolor Capsule 500mg Each Capsule Contains: Cefaclor…500mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
671.	049455	Neudoxine Capsule Each Capsule Contains: Cefpodoxime as Proxetil…100mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
672.	049456	Otim Capsule Each Capsule Contains: Cefuroxime as Axetil…250mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
673.	049457	Tefra Capsule 500mg Each Capsule Contains: Cefradine as Monohydrate…500mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
674.	049458	Tefra Dry Suspension Each 5ml Contains: Cefradine as Monohydrate 125mg	15-07-2008	Dy. No. 24174 dated 12-07-2018 10000/-		-do-
675.	049459	Otim Dry Suspension Each 5ml Contains: Cefuroxime as Axetil…125mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
676.	049460	Neulexin Dry Suspension Each 5ml Contains: Cefalexin as Monohydrate…125mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
677.	049461	Serve Dry Suspension 100mg Each 5ml Contains: Cefixime as Trihydrate…100mg	15-07-2008 Change of brand name: 22-04-2009	Dy. No. 24174 12-07-2018 10000/-		-do-
678.	049462	Serve Dry Suspension 200mg Each 5ml Contains: Cefixime as Trihydrate…200mg	15-07-2008 Change of brand name: 22-04-2009	Dy. No. 24174 12-07-2018 10000/-		-do-
679.	049463	Neuprozil Dry Suspension Each 5ml Contains: Cefprozil as Monohydrate…125mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
680.	049464	Neutroclor Dry Suspension Each 5ml Contains: Cefaclor as Monohydrate…125mg	15-07-2008	Dy. No. 24174 12-07-2018 10000/-		-do-
681.	049465	Actacef Dry Suspension 125mg Each 5ml Contains:	15-07-2008 Change of brand name:	Dy. No. 24174 12-07-2018 10000/-		-do-

		Cefadroxil as Monohydrate…125mg	22-04-2009			
iv. **M/s. Spencer & Company (Pvt) Ltd, D-105, S.I.T.E., Karachi**						
682.	030856	Diflubid Tablets 500mg Each tablet contains: Diflunisal……..500mg	12-08-2003	Dy. No. 25869 26-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.
683.	014283	Polygard Tablet 250mg Each Tablet Contains: Ciprofloxacin HCl Monohydrate 250mg eq. to Ciprofloxacin 250mg Base	05-08-1993	Dy. No. 25868 26-07-2018 10000/-		-do-
M/s. Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad						
684.	050285	Respimet Syrup. Each 1ml contains: Ketotifen as Fumarate……0.2mg.	28-07-2008	Dy. No. 25824 26-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.
685.	050286	Silicur Tablets. Each tablet contains: Silymarin……. 200mg	28-07-2008	Dy. No. 25824 26-07-2018 10000/-		-do-
686.	050287	Sycon Tablet 3mg. Each film coated Tablet contains: Risperidone……3mg.	28-07-2008	Dy. No. 25824 26-07-2018 10000/-		-do-
687.	050288	Sycon Tablets 4mg. Each film coated Tablet contains: Risperidone……4mg	28-07-2008	Dy. No. 25824 26-07-2018 10000/-		-do-
688.	050986	Polymat Syrup Each 15ml contains: Iron Protein Succinylate……...800mg (eq to 40mg elemental iron)	12-08-2008	Dy. No. 25824 26-07-2018 10000/-		-do-
M/s. Drug's Inn, 1-I, Parkview Plaza, Markaz F-10, Islamabad						
689.	028464	Brunac Eye Drops Each 100ml Contains: N-Acetylcysteine…5gm	19-07-2003	Dy. No. 24488 13-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 which has not yet been responded by the firm.
v. **M/s. WellbornePharmachem&Biologicals, Plot 51/1, 52/2 Phase I&II Industrial Estate, Hattar**						

690.	77412	Mycophenol 500 mg Tablets Each film coated tablet contains: Mycophenolate Mofetil…...500 mg	23-07-2013	Dy. No. 23436 dated 06-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 6-3-2019 which has not yet been responded by the firm.
691.	77411	D-Well Injection Each 1 ml contains: Cholecalciferol…5 mg (200,000.I.U.)	12-06-2013	Dy. No. 23218 05-07-2018 10000/-		-do-
M/s. Sharex Laboratories Ltd., K.L.P. Road, Sharex Colony Sadiqabad, Distt. Rahim Yar Khan.						
692.	14209	Anaren Tablet Each Tablet Contains: Diclofenac Sodium…50mg	05-08-1993	Dy. No. 25634 24-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 7-3-2019 which has not yet been responded by the firm.
693.	14210	Anaren Injection Each 3ml Contains: Diclofenac Sodium…75mg	05-08-1993	Dy. No. 25635 24-07-2018 10000/-		-do-
694.	22259	Bibcol Drops Each ml Contains: Activated Dimethicone…10mg Xanthun Gum…2.5mg	31-08-1998	Dy. No. 25636 24-07-2018 10000/-		-do-
M/s. Trigon Pharmaceuticals (Pvt) Ltd., 8-Km Thokar Raiwind Road, Lahore						
695.	049991	Aquanone Cream Contains: Hydroquinone…4%w/w	19-07-2008	Dy. No. 25027 dated 18-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 7-3-2019 which has not yet been responded by the firm.
696.	49992	Cefegon Dry Powder Injection 1gm Each Vial Contains: Cefepime as HCl…1gm	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
697.	49993	Cefegon Dry Powder Injection 500mg Each Vial Contains: Cefepime as HCl…500mg	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
698.	49994	Bugnil Infusion Each 100ml Vial Contains: Ofloxacin as HCl…200mg	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
699.	49995	Trirome Dry Powder Injection Each Vial Contains: Cefpirome as Sulphate…500mg	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-

700.	49997	Moxilox Tablet 400mg Each Film Coated Tablet Contains: Moxifloxacin…400mg	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
701.	49998	Trikiln Vaginal Cream Each Tube Contains: Clindamycin as Phosphate…2%	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
702.	49999	Dorcip Tablet 500mg Each Tablet Contains: Ciprofloxacin as HCl…500mg	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
703.	50000	Dorcip Tablet 250mg Each Tablet Contains: Ciprofloxacin as HCl…250mg	19-07-2008	Dy. No. 25027 18-07-2018 10000/-		-do-
M/s. Murfy Pharmaceuticals (Pvt) Ltd., 8-Km Raiwind Road, Lahore.						
704.	49910	Flamo-Nil Cream Each 100gm Contains: Silver Sulphadiazine…1gm	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 6-3-2019 which has not yet been responded by the firm.
705.	49911	Gentadin Cream Each gm Contains: Gentamycin as Sulphate…0.1%w/w	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
706.	49912	Polyrex Ointment Each gm Contains: Polymyxin B Sulphate…10,000IU Bacitracin Zinc…500IU	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
707.	49913	Clotrexem Cream Each 100gm Contains: Clotrimazole…1gm	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
708.	49914	Ibufil Cream Each 100gm Contains: Ibuprofen…10gm	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
709.	49915	Vaporex Balm Each 100gm Contains: Methyl Salicylate…12.17gm	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
710.	49916	Somex Gel Each gm Contains: Lignocaine Base…0.6%w/w	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
711.	49917	Diclofil Gel Each 100gm Contains: Diclofenac Diethyl ammonium Salt eq. to Diclofenac Sodium…2gm	17-07-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
712.	52977	Lincomin DS Capsule 500mg Each Capsule Contains:	27-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-

		Lincomycin HCl eq. to Lincomycin…500mg				
713.	52978	Lopramex Capsule 2mg Each Capsule Contains: Loperamide HCl…2mg	27-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
714.	52979	Piroxil Capsule 20mg Each Capsule Contains: Piroxicam…20mg	27-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
715.	52982	Diclofil Capsule 50mg Each Capsule Contains: Diclofenac Sodium Enteric Coated Pellets of eq. to Diclofenac Sodium…500mg	28-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
716.	52983	Diclofil SR Capsule 100mg Each Capsule Contains: Diclofenac Sodium Sustained Released Pellets eq. to Diclofenac Sodium…100mg	28-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
717.	52984	Omeprin Capsule 20mg Each Capsule Contains: Omeprazole Enteric Coated Pellets eq. to Omeprazole…20mg	28-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
718.	52985	Omeprin Capsule 40mg Each Capsule Contains: Omeprazole Enteric Coated Pellets eq. to Omeprazole…40mg	28-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
719.	52986	Esomeprin Capsule 20mg Each Capsule Contains: Esomeprazole Enteric Coated Pellets Magnesium Trihydrate eq. to Esomeprazole…20mg	28-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
720.	52987	Esomeprin Capsule 40mg Each Capsule Contains: Esomeprazole Enteric Coated Pellets Magnesium Trihydrate eq. to Esomeprazole…40mg	28-11-2008	Dy. No. 22999 03-07-2018 10000/-		-do-
M/s. Oval Pharmaceuticals, 112/11, Industrial Estate, Township, Lahore						
721.	49923	Reofen Suspension Each 5ml Contains: Ibuprofen…100mg	17-07-2008	Dy. No. 24626 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 6-3-2019 which has not yet been responded by the firm.
722.	49924	Silvone Cream 50gm Each Tube Contains: Silver Sulphadiazine…1%w/w	17-07-2008	Dy. No. 24626 16-07-2018 10000/-		-do-
723.	49928	Monocaine Gel 15gm	17-07-2008	Dy. No. 24626		-do-

		Each gm Contains: Lidocaine HCl…2%w/w		16-07-2018 10000/-		
724.	49929	Xettol Antiseptic Solution Contains: Chloroxylenol Solution…50%v/v	17-07-2008	Dy. No. 24626 16-07-2018 10000/-		-do-
725.	49930	Iodine CMS Ointment 15gm Each Tube Contains: Polymyxin Iodine…4%w/w Methyl Salicylate…5%w/w	17-07-2008	Dy. No. 24626 16-07-2018 10000/-		-do-
726.	49931	Polymalt-III Syrup Each 5ml Contains: Iron (as Hydroxide Polymaltose)…50mg	17-07-2008	Dy. No. 24626 16-07-2018 10000/-		-do-
727.	49925	Septodine Antiseptic Solution Each 100ml Contains: Povidone Iodine…10gm	17-07-2008	Dy. No. 24626 16-07-2018 10000/-		-do-
M/s. Friends Pharma (Pvt) Ltd., 31-Km, Ferozepur Road, Lahore						
728.	050136	Intelect Tablet Each Tablet Contains: Citalopram as HBr…20mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 6-3-2019 which has not yet been responded by the firm.
729.	50137	Regainol Tablet Each Tablet Contains: Tizanidine as HCl…2mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
730.	50139	Rounder Capsule Each Capsule Contains: Cefdinir…100mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
731.	50140	Rounder Suspension Each 5ml Contains: Cefdinir…50mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
732.	50141	Bactirol Tablet Each Tablet Contains: Moxifloxacin HCl…400mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
733.	50142	Trendone Tablet 1mg Each Tablet Contains: Risperidone…1mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
734.	50143	Trendone Tablet 2mg Each Tablet Contains: Risperidone…2mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
735.	50144	Brainagol Tablet Each Tablet Contains: Olanzapine…5mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
736.	50145	Loctal Capsule Each Capsule Contains: Gabapentin…300mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
737.	50146	Fledonil Capsule Each Capsule Contains: Tranexamic Acid…500mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
738.	50147	Ritopar Tablet	23-07-2008	Dy. No. 25307		-do-

		Each Tablet Contains: Ritodrine HCl…10mg		20-07-2018 10000/-		
739.	50148	Loctal Capsule Each Capsule Contains: Gabapentin…100mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
740.	50149	Peprozol Tablet Each Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-		-do-
M/s. Siza International (Pvt) Ltd., 18-Km Lahore Kasur Road, Dist. Kasur						
741.	9888	Propranolol HCl 40mg Tab Each Tablet Contains: Propranolol HCl 40mg	19-09-1988	Dy. No. 25524 25-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 6-3-2019 which has not yet been responded by the firm.
742.	10014	Dextrose 25% W/V Inj Each 1000ml Infusion Contains: Dextrose Anhydrous 250gms	30-09-1988	Dy. No. 25524 25-07-2018 10000/-		-do-
743.	14214	Carsine 10mg Tablet Each Tablet Contains: Tamoxifen…10mg	05-08-1993	Dy. No. 25524 25-07-2018 10000/-		-do-
744.	30883	Prava Tablets Each tablet contains: Pravastatin Sodium…..20mg	12-08-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
745.	30884	Convul SR Tablets 400mg Each tablet contains: Carbamazepine BP……400mg	12-08-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
746.	30885	Numbaix Injection 25mg Each 2.5ml contains: Atracurium Besylate ….25mg	12-08-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
747.	30886	Dupophen 25mg Injection Each 1ml ampoule contains: FluphenazineDecanoate…. 25mg	28-08-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
748.	30887	Ahyal 10mg Injection Each ml contains: Sodium Hyaluronate …10mg	28-08-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
749.	31959	Dibent Capsule 250mg Each capsule contains: Cefatrizine (as Cefatrizine Propylene Glycol)……..250mg	11-12-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
750.	31960	Dibent Capsule 500mg Each capsule contains: Cefatrizine (as Cefatrizine Propylene	11-12-2003	Dy. No. 25524 25-07-2018 10000/-		-do-

		Glycol)……..500mg				
751.	31961	Dibent Suspension 250mg Each 5ml contains: Cefatrizine (as Cefatrizine Propylene Glycol)……..250mg	11-12-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
752.	31962	Sopra 30mg Capsules Each capsule contains: Lansoprazole ……30mg	11-12-2003	Dy. No. 25524 25-07-2018 10000/-		-do-
753.	50868	Supren 250mg Suspension. Each 5ml Contains: Cefaclor as Monohydrate …….250mg (USP Specs)	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
754.	50869	Supren 125mg Suspension. Each 5ml Contains: Cefaclor as Monohydrate ….125mg (USP Specs)	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
755.	50870	Ecanx 7.5mg Tablets. Each Tablet Contains: Meloxicam……7.5mg. (BP Specs)	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
756.	50871	Ecanx 15mg Tablets. Each Tablet Contains: Meloxicam……15mg. (BP Specs)	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
757.	50872	Lukrx 5mg Tablets. Each Tablet Contains: Montelukast as Sodium……5mg	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
758.	50873	Lukrx 10mg Tablets. Each Tablet Contains: Montelukast as Sodium……10mg.	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
759.	50874	Deslorat 5mg Tablets. Each Film Coated Tablet Contains: Desloratadine……5mg.	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
760.	50875	Xyfex 120mg Tablets. Each Tablet Contains: Fexofenadine HCl……120mg.	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
761.	50876	Siflogem 320mg Tablets. Each Film Coated Tablet Contains: Gemifloxacin as Mesylate…….320mg.	02-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
762.	51052	Ezumac Capsules 20mg. Each Capsule contains: Esomeprazole as Magnesium trihydrate…20mg.	18-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
763.	51053	Ezumac Capsules 40mg. Each Capsule contains: Esomeprazole as Magnesium trihydrate…40mg.	18-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-

764.	51108	Glosiflox 400mg Infusion. Each 250ml Vial Contains: Moxifloxacin as HCl……400mg.	23-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
765.	51109	Glosiflox Tablets 400mg. Each Film Coated Tablet Contains: Moxifloxacin as HCl……400mg	23-08-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
766.	52491	Lukrx Chewable 4mg Tablets. Each Tablet Contains: Montelukast as Sodium……..……4mg	17-09-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
767.	53681	Oredx 40mg Suspension Each 5ml contains: Cefpodoxime Proxetil eq. to Cefpodoxime 40mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
768.	53682	Xurox125mg Suspension Each 5ml contains: Cefuroxime Axetil eq. to Cefuroxime 125mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
769.	53683	Kalsartan 50mg Tablet Each Film Coated Tablet Contains: Losartan Potassium 50mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
770.	53684	Kalsartan-H Tablet Each Film Coated Tablet Contains: Losartan Potassium ..... 50mg, Hydrochlorothiazide..... 12.5mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
771.	53685	Mecoza 500mcg Tablet Each tablet contains: Mecobalamin (Vitamin B12) 500mcg	06-12-2008 Change of brand name dated: 21-4-2009	Dy. No. 25524 25-07-2018 10000/-		-do-
772.	53686	Mecoza 500mcg Injection Each ml contains: Mecobalamin (Vitamin B12) 500mcg	06-12-2008 Change of brand name dated: 21-4-2009	Dy. No. 25524 25-07-2018 10000/-		-do-
773.	53687	Zacol 0.5mcg Tablet Each tablet contains: Alfacalcidol (Vitamin D) 0.5mcg	06-12-2008 Change of brand name dated: 21-4-2009 Correction in registration No. dated 06-07-2010	Dy. No. 25524 25-07-2018 10000/-		-do-
774.	53688	Ferrux 100mg Tablet Each tablet contains: Iron Hydroxide Polymaltose Complex	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-

		100mg				
775.	53689	Ferrux-F 100mg Tablet Each Chewable Tablet Contains: Iron Polymaltose Complex eq. to Elemental Iron ..... 100mg, Folic Acid..... 0.35mg	06-12-2008 Correction in brand name dated: 22-8-2009	Dy. No. 25524 25-07-2018 10000/-		-do-
776.	53690	Iroxin 20mg Injection Each ml contains: Iron Sucrose Complex eq. to Elemental Iron 20mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
777.	53691	Gliza 1mg Tablet Each tablet contains: Glimepiride 1mg	06-12-2008 Change of brand name dated: 21-4-2009	Dy. No. 25524 25-07-2018 10000/-		-do-
778.	53692	Gliza 2mg Tablet Each tablet contains: Glimepiride 2mg	06-12-2008 Change of brand name dated: 21-4-2009	Dy. No. 25524 25-07-2018 10000/-		-do-
779.	53693	Gliza 4mg Tablet Each tablet contains: Glimepiride 4mg	06-12-2008 Change of brand name dated: 21-4-2009	Dy. No. 25524 25-07-2018 10000/-		-do-
780.	53694	Atroclor 10mg Tablet Each Film Coated Tablet Contains: Atorvastatin Calcium eq. to Atorvastatin 10mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
781.	53695	Atroclor 20mg Tablet Each Film Coated Tablet Contains: Atorvastatin Calcium eq. to Atorvastatin 20mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
782.	53696	Atroclor 40mg Tablet Each Film Coated Tablet Contains: Atorvastatin Calcium eq. to Atorvastatin 40mg	06-12-2008	Dy. No. 25524 25-07-2018 10000/-		-do-
M/s. Focus &Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad						
783.	49294	Lakas 10mg Tablet Each Tablet Contains: Montelukast as Sodium…10mg	10-07-2008	Dy. No. 23142 04-07-2018 10000/-		Evidence of change of brand name is required.
784.	49327	Cephcef Dry Suspension 250mg Each 5ml Contains: Cephradine…250mg	10-07-2008	Dy. No. 23165 04-07-2018 10000/-		
785.	49326	Cephcef Dry Suspension 125mg Each 5ml Contains: Cephradine…125mg	10-07-2008	Dy. No. 23164 04-07-2018 10000/-		Approval of formulation in reference agencies is not submitted.
786.	49329	Exodril Dry Suspension 125mg	10-07-2008	Dy. No. 23170 04-07-2018		Evidence of change of brand

		Each 5ml Contains: Cefadroxil…125mg		10000/-		name is required.
787.	49318	Exodril Capsule 500mg Each Capsule Contains: Cefadroxil…500mg	10-07-2008	Dy. No. 23168 04-07-2018 10000/-		Evidence of change of brand name is required.
788.	49328	Exodril Dry Suspension 250mg Each 5ml Contains: Cefadroxil…250mg	10-07-2008	Dy. No. 23169 04-07-2018 10000/-		Evidence of change of brand name is required.
789.	49288	Esro 40mg Capsule Each Capsule Contains: Esomeprazole as Magnesium Trihydrate Enteric Coated Pellets…40mg	10-07-2008	Dy. No. 23161 04-07-2018 10000/-		Evidence of change of brand name is required. Differential fee for imported pellets is not submitted.
790.	49287	Esro 20mg Capsule Each Capsule Contains: Esomeprazole as Magnesium Trihydrate Enteric Coated Pellets…20mg	10-07-2008	Dy. No. 23160 04-07-2018 10000/-		Evidence of change of brand name is required. Approval of change of source of pellets is not submitted; however copy of application dated 02-02-2012 for change source of pellets from import to local is submitted. Firm also denied to submit differential fee.
791.	49289	Omper 20mg Capsule Each Capsule Contains: Omeprazole as Enteric Coated Pellets…20mg	10-07-2008	Dy. No. 23159 04-07-2018 10000/-		Approval of change of source of pellets is not submitted; however copy of application dated 02-02-2012 for change source of pellets from import to local is submitted. Firm also denied to submit the differential fee.
M/s. Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone (RCCI) Rawat						
792.	50023	Isobact Cream Each gm Contains: Isoconazole Nitrate…10mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 7-3-2019 which has not yet been responded by the firm.
793.	50024	Fusiway-B Cream	19-07-2008	Dy. No. 24521		-do-

		Each gm Contains: Fusidic Acid…20mg Betamethasone as Valerate…1mg		16-07-2018 10000/-		
794.	50025	Fusiway-H Cream Each gm Contains: Fusidic Acid…20mg Hydrocortisone as Acetate…10mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
795.	50026	Myface Cream Each gm Contains: Tretinoin…0.5mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
796.	50027	Cef-Na 1gm Injection Each Vial Contains: Cefoperazone as Sodium…500mg Salbactum as Sodium…500mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
797.	50028	Cef-Na 2gm Injection Each Vial Contains: Cefoperazone as Sodium…1gm Salbactum as Sodium…1gm	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
798.	50029	Biamad Injection 250mg Each Vial Contains: Ceftazidime…250mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
799.	50030	Biamad Injection 1gm Each Vial Contains: Ceftazidime…1gm	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
800.	50031	Cef Moon Injection IM 250mg Each Vial Contains: Ceftriaxone as Sodium…250mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
801.	50032	Cef Moon Injection IM 500mg Each Vial Contains: Ceftriaxone as Sodium…500mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
802.	50033	Cef Moon Injection IM 1gm Each Vial Contains: Ceftriaxone as Sodium…1gm	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
803.	50034	Carapime Injection 1gm Each Vial Contains: Cefepime…1gm	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
804.	50035	Carapime Injection 500gm Each Vial Contains: Cefepime…500mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
805.	50036	Hylaform Injection 250mg Each Vial Contains: Cefotaxime as Sodium…250mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
806.	50037	Hylaform Injection 1gm Each Vial Contains:	19-07-2008	Dy. No. 24521 16-07-2018		-do-

		Cefotaxime as Sodium…1gm		10000/-		
807.	50038	Amifate Injection 100mg Each 2ml Contains: Amikacin as Sulphate…100mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
808.	50039	Amifate Injection 250mg Each 2ml Contains: Amikacin as Sulphate…250mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
809.	50040	Amifate Injection 500mg Each 2ml Contains: Amikacin as Sulphate…500mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
810.	50041	Mecorise Injection 500mcg Each ml Contains: Mecobalamin…500mcg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
811.	50042	Citograin Injection Each 2ml Contains: Citicoline as Sodium…250mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
812.	50043	Surmount Infusion Each 100ml Contains: Levofloxacin as Hemihydrate…250mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
813.	50044	Caralox Infusion Each 100ml Contains: Ciprofloxacin as Lactate…200mg	19-07-2008	Dy. No. 24521 16-07-2018 10000/-		-do-
814.	50045	Topcal Tablet 50mg Each Tablet Contains: Topiramate…50mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
815.	50046	Topcal Tablet 100mg Each Tablet Contains: Topiramate…100mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
816.	50047	Topmate Tablet 400mg Each Tablet Contains: Pefloxacin…400mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
817.	50048	Caramount Tablet 5mg Each Tablet Contains: Mountelukast…5mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
818.	50049	Caramount Tablet 10mg Each Tablet Contains: Mountelukast…10mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
819.	50050	Ranisifar Tablet Each Tablet Contains: Ranitidine as HCl…150mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
820.	50051	Resigrin Tablet 1mg Each Tablet Contains: Resperidone…1mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
821.	50052	Resigrin Tablet 2mg Each Tablet Contains: Resperidone…2mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
822.	50053	Resigrin Tablet 3mg Each Tablet Contains: Resperidone…3mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
823.	50054	Metadox Tablet 500mg	19-07-2008	Dy. No. 24774		-do-

		Each Tablet Contains: Metformin HCl…500mg		17-07-2018 10000/-		
824.	50055	Metadox Tablet 850mg Each Tablet Contains: Metformin HCl…850mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
825.	50056	Metadox Tablet 1000mg Each Tablet Contains: Metformin HCl…1000mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
826.	50057	Esitaraway Tablet 10mg Each Tablet Contains: Escitalopram as Oxalate…10mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
827.	50058	Olimag Tablet 5mg Each Tablet Contains: Olanzapine…5mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
828.	50059	Olimag Tablet 10mg Each Tablet Contains: Olanzapine…10mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
829.	50060	Modivid Tablet Each Tablet Contains: Piroxicam as Beta-Cyclodextrin…20mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
830.	50061	Oridox Tablet Each Tablet Contains: Cefpodoxime as Paroxetil…100mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
831.	50062	Lefluno Tablet 10mg Each Tablet Contains: Leflunomide…10mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
832.	50063	Lefluno Tablet 20mg Each Tablet Contains: Leflunomide…20mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
833.	50064	IHP Tablet Each Tablet Contains: Iron as eq. to Elemental Iron Polymaltose Complex…100mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
834.	50065	IHP-F Tablet Each Tablet Contains: Iron as eq. to Elemental Iron Polymaltas…100mg Folic Acid…0.35mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
835.	50066	Metorate Lotion 20ml Each Bottle Contains: MometasoneFurate…1mg	19-07-2008	Dy. No. 24774 17-07-2018 10000/-		-do-
836.	50067	Cefeye Suspension Each 5ml Contains: Cefdinir…50mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
837.	50068	Cinotec Suspension Each 5ml Contains: Cefpodoxime…40mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
838.	50069	Caradin Suspension Each 5ml Contains: Cephradine…125mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
839.	50070	Caradin DS Suspension Each 5ml Contains: Cephradine…250mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-

840.	50071	Azitrix Suspension Each 5ml Contains: Azithromycin…200mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
841.	50072	Claromin Suspension Each 5ml Contains: Clarithromycin…125mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
842.	50073	Regab Capsule 50mg Each Capsule Contains: Pregablin…50mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
843.	50074	Regab Capsule 100mg Each Capsule Contains: Pregablin…100mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
844.	50075	Regab Capsule 75mg Each Capsule Contains: Pregablin…75mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
845.	50076	Regab Capsule 150mg Each Capsule Contains: Pregablin…150mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
846.	50078	Caradine Injection 1gm Each Vial Contains: Cephradine…1gm	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
847.	50079	Caradine Injection 500mg Each Vial Contains: Cephradine…500mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
848.	50080	Lictyn Injection 250mg Each Vial Contains: Cefuroxime as Axetil…250mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
849.	50081	Lictyn Injection 750mg Each Vial Contains: Cefuroxime as Axetil…750mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
850.	50082	Caradine Injection 250mg Each Vial Contains: Cephradine…250mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
851.	50083	Caramether Injection Each Vial Contains: Artemether…80mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
852.	50084	Triway Injection Each 1ml Ampoule Contains: Triamcinolone Acetonide…40mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
853.	50085	Carawat Injection Contains: Water for Injection	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
854.	50086	Calyperol Injection Each Vial Contains: Ketamine HCl…50mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
855.	50087	Metrodex Infusion 500mg Each Vial Contains: Metronidazole…500mg/10 0ml	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
856.	50088	Surmont Infusion 500mg Each Vial Contains: Levofloxacin as Hemihydrate…500mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-

857.	50089	Topestin Infusion Each Vial Contains: Pefloxacin…400mg	19-07-2008	Dy. No. 25036 18-07-2018 10000/-		-do-
858.	50807	Azitrix Capsules 20mg. Each Capsule Contains: Omeprazole as enteric coated pellets……20mg. (USP Specs)	29-07-2008	Dy. No. 26014 27-07-2018 20000/-		-do-
859.	50808	Caralans Capsules 15mg. Each Capsule Contains: Lansoprazole as enteric coated Pellets……15mg. (USP Specs)	29-07-2008	Dy. No. 26014 27-07-2018 20000/-		-do-
860.	50809	Caralans Capsules 30mg. Each Capsule Contains: Lansoprazole as enteric coated Pellets……30mg. (USP Specs)	29-07-2008	Dy. No. 26014 27-07-2018 20000/-		-do-
861.	50810	Vogue Capsules 20mg. Each Capsule Contains: Esomeprazole as magnesium trihydrate enteric coated Pellets……..20mg.	29-07-2008	Dy. No. 26014 27-07-2018 20000/-		-do-
862.	50811	Vogue DS Capsules 40mg. Each Capsule Contains: Esomeprazole as magnesium trihydrate enteric coated Pellets……..40mg.	29-07-2008	Dy. No. 26014 27-07-2018 20000/-		-do-
863.	50001	Fludecate 20 Capsules. Each Capsule Contains: Fluoxetine as HCl …20mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
864.	50002	Azitrix 250mg Capsules. Each Capsule Contains: Azithromycin as dehydrate……250mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
865.	50003	Cefaben Capsules. Each Capsule Contains: Cefixime……200mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
866.	50004	Cefaben DS Capsules. Each Capsule Contains: Cefixime ……400mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
867.	50005	Cefaben Suspension. Each 5ml Contains: Cefexime …….100mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
868.	50006	Cefaben DS Suspension. Each 5ml Contains: Cefexime …….200mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
869.	50007	Surmount Tablets 250mg. Each Tablet Contains: Levofloxacin as Hemihydrate…..250mg	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
870.	50008	Surmount Tablets 500mg. Each Tablet Contains:	19-07-2008	Dy. No. 23687 09-07-2018		-do-

		Levofloxacin as Hemihydrate…..500mg		10000/-		
871.	50009	Lomerol Tablets 400mg. Each Tablet Contains: Lomefloxacin as HCl.....400mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
872.	50010	Claromin Tablets 250mg. Each Tablet Contains: Clarithromycin ….250mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
873.	50011	Claromin Tablets 500mg. Each Tablet Contains: Clarithromycin ..500mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
874.	50012	Caralox Tablets 250mg. Each Tablet Contains: Ciprofloxacin as HCl …….250mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
875.	50013	Caralox Tablets 500mg. Each Tablet Contains: Ciprofloxacin as HCl …….500mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
876.	50014	Caramither Plus Tablets. Each Tablet Contains : Artemether…….20mg. Lumefantrine….120mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
877.	50015	Mecorize Tablets 500mcg. Each Tablet Contains: Mecobalamin…..500mcg	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
878.	50016	Licide Tablets Each Tablet Contains: Levocetrizine 2HCl..5mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
879.	50017	Feldax Tablets. Each Tablet Contains: Flurbiprofen ……100mg. (BP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
880.	50018	Carafenac-P Tablets 50mg. Each Tablet Contains: Diclofenac Potassium ……..50mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
881.	50019	Carafenac-P Tablets 75mg. Each Tablet Contains: Diclofenac Potassium …..75mg. (USP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
882.	50020	Myxole Cream. Each Gram Contains: Ketoconazole …..20mg.	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
883.	50021	Fusiway Cream. Each Gram Contains: Fusidic Acid …….20mg. (BP Specs)	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-
884.	50022	Caracort Cream. Each Gram Contains: Miconazole Nitrate……20mg. Hydrocortisone as	19-07-2008	Dy. No. 23687 09-07-2018 10000/-		-do-

		acetate…..10mg. (BP Specs)				
M/s. Curatech Pharma (Pvt) Ltd., 35-Km Multan Road, Lahore						
885.	049467	Melather DS tablets Each tablet contains: Artemether 40mg Lumefantrine 240mg	15-07-2008	Dy. No. 24517 16-07-2018 10000/-		The firm submitted that their renewal fee was submitted one day late due to weekly holiday.
886.	049466	Zanitech tablet 2mg Each tablet contains: Tizanidine as HCL 2mg	15-07-2008	Dy. No. 24517 16-07-2018 10000/-		-do-
887.	049470	Sudoproxim Tablet Each tablet contains: Ibuprofen 200mg Pseudoephedrine HCL 30mg	15-07-2008	Dy. No. 24517 16-07-2018 10000/-		-do-
888.	049471	Sudoproxim Tablet Each tablet contains: Ibuprofen 400mg Pseudoephedrine HCL 60mg	15-07-2008	Dy. No. 24517 16-07-2018 10000/-		-do-
M/s. Medipak Ltd., 132 Industrial Estate, Kot Lakhpat Lahore						
889.	010005	Medigyl injection 0.5% Each 100ml contains: Metroidazole 500mg sodium chloride 740mg	31-10-1988	Dy. No. 24512 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 11-3-2019 which has not yet been responded by the firm.
890.	014260	Aqura Sterile Injection Water for Injection	05-08-1993	Dy. No. 24518 16-07-2018 10000/-		-do-
M/s. Wahabson Pharma (Pvt) Ltd., 4-Km Buner Road, Barikot, Swat						
891.	052710	Kymol Suspension Each 5ml Contains: Paracetamol…120mg	22-10-2008	Dy. No. 25248 19-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 27-2-2018 which has not yet been responded by the firm.
892.	052711	Kymol Forte Suspension Each 5ml Contains: Paracetamol…250mg	22-10-2008	Dy. No. 25248 19-07-2018 10000/-		-do-
893.	052712	Wydryllin DM Syrup Each 5ml Contains: Diphenhydramine…5mg Dextromethorphan..6.25mg	22-10-2008	Dy. No. 25248 19-07-2018 10000/-		-do-
894.	052713	Wormnor Suspension Each 5ml Contains: Albendazole…100mg	22-10-2008	Dy. No. 25248 19-07-2018 10000/-		-do-
895.	052714	Walidix Suspension	22-10-2008	Dy. No. 25248		-do-

		Each 5ml Contains: Nalidixic Acid…250mg		19-07-2018 10000/-		
M/s. Shaheen Pharmaceuticals, 3-Km Murghzar Road, Saidu Sharif, Sawat						
896.	49330	Lanosh Capsules. Each Enteric Coated Capsule Contains: Lansoprazole Pellets eq. to Lansoprazole .....30mg. (USP Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 14-3-2019 which has not yet been responded by the firm.
897.	49331	Zoger Capsules. Each enteric coated capsule contains Omeprazole Pellets eq. to Omeprazole……20mg. (USP Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
898.	49367	Dequit 25mg Tablets. Each Tablet Contains: Quetiapine Fumarate eq. to Quetiapine……..25mg.	11-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
899.	49368	Dequit 200mg Tablets. Each Tablet Contains: Quetiapine Fumarate eq. to Quetiapine……..200mg.	11-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
900.	49332	Pepnor 20mg Tablets. Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate …….20mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
901.	49333	Pepnor 40mg Tablets. Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate…….40mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
902.	49334	Shalox Tablets. Each Tablet Contains: Moxifloxacin HCl……..400mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
903.	49335	Rager Tablets. Each Enteric Coated tablet Contains: Rabeprazole Sodium……..20mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
904.	49336	Alenat Tablets. Each Tablet Contains: Alendronate as Sodium .....70mg (USP Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
905.	49337	Cyclodor Tablets. Each Tablet Contains: Piroxicam B-Cyclodextrine eq. to Piroxicam…20mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
906.	49338	Ocedep 50mg Tablets.	10-07-2008	Dy. No. 23230		-do-

		Each Tablet Contains: Fluvoxamine Maleate BP……50mg. (B.P Specs)		05-07-2018 10000/-		
907.	49339	Ocedep 100mg Tablets. Each Tablet Contains: Fluvoxamine Maleate ……100mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
908.	49340	Preston 250mg Tablets. Each Tablet Contains: Mefenamic Acid ..250mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
909.	49341	Preston Forte 500mg Tablets. Each Tablet Contains: Mefenamic Acid ..500mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
910.	49342	Butral 10mg Tablets. Each Tablet Contains: Bambuterol ……10mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
911.	49343	Butral 20mg Tablets. Each Tablet Contains: Bambuterol ……20mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
912.	49344	Normidol Tablets. Each Tablet Contains: Paracetamol ….500mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
913.	49345	Curedol Extra Tablets. Each Tablet Contains: Paracetamol …500mg. Caffeine …….65mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
914.	49346	Dequit 100mg Tablets. Each Tablet Contains: Quetiapine Fumarate eq. to Quetiapine……..100mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-		-do-
M/s. Nawabsons Laboratories (Pvt) Ltd., Jia Bagga, Off Raiwind Road, Lahore						
915.	49932	Hemogrel tablets 75mg Each film coated tablet contains: Clopidogrel Bisulphate 75mg	17-07-2008	Dy. No. 24509 16-07-2018 10000/-		Evidence of submission of last renewal (2013) is required
916.	49933	Roastatin tablet 20mg Each film coated tablet contains: Atorvastatin as calcium 20mg	17-07-2008	Dy. No. 24509 16-07-2018 10000/-		-do-
917.	49935	Roastatin tablet 10mg Each film coated tablet contains: Atorvastatin as calcium 10mg	17-07-2008	Dy. No. 24509 16-07-2018 10000/-		-do-
918.	49937	S/S Cream :		Dy. No. 24509 16-07-2018 10000/-		-do-
919.	49938	Methyl Salicylate Liniment		Dy. No. 24509		-do-

		:		16-07-2018 10000/-		
M/s. Swat Pharmaceuticals, Saidu Sharif, Swat, 19130 KPK						
920.	77415	Zeromel DS Tablet Each Tablet Contains: Artemether…40mg Lumefantrine…240mg	04-07-2013	Dy. No. 22793 02-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 14-3-2019 which has not yet been responded by the firm.
921.	77416	Zeromel Tablet Each Tablet Contains: Artemether…20mg Lumefantrine…120mg	04-07-2013	Dy. No. 22792 02-07-2018 10000/-		-do-
922.	21627	Allorin Tablet Each Tablet Contains: Chlorpheniramine Maleate…4mg	20-05-1998	Dy. No. 24507 16-07-2018 20000/-		-do-
M/s. Zinta Pharmaceutical Industry, 168-Industrial Estate, Hayatabad, Peshawar						
923.	051067	Cyprectin Syrup Each 5ml Contains: Cyproheptadine HCl…2mg	20-08-2008	Dy. No. 24520 16-07-2018 10000/-		Application is not submitted in Form-5B. Last renewal is not submitted. GMP compliance is not on acceptable level as per FID report dated 20-2-2018. Valid DML is snot submitted instead copy of application for renewal in 2015 is provided.
M/s. Venus Pharma, 23-Km Multan Road, Lahore						
924.	013993	Xylex 2% Injection with Adrenaline Contains: Lignocaine HCl…2%w/v Adrenaline…0.001%w/v	28-07-1993	Dy. No. 24679 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 19-3-2019 which has not yet been responded by the firm.
M/s. Lawrence Pharma (Pvt) Ltd., 10.5-Km Sheikhupura Road, Lahore						
925.	014720	Lawrplex Forte Injection Each 3ml Ampoule Contains: Thiamine HCl…100mg Pyridoxine HCl…100mg Cyanocobalamin..1000mcg	24-11-1993	Dy. No. 25146 19-07-2018 10000/-		Letter of shortcomings was issued to firm vide letter No. F.1-65/ 2018 (RRR) dated 22-3-2019 which has not yet been responded by firm.
926.	050203	Sarbomol Injection.	24-07-2008	Dy. No. 25145		-do-

		Each 1ml ampoule contains: Salbutamol as Sulphate……0.5mg (BP Specs)		19-07-2018 10000/-		
927.	050204	Lawrmazin Injection. Each 1ml contains: Promethazine as HCl…….25mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
928.	050205	Xathonium Injection. Each ml Ampoule contains: Suxamethonium Chloride……..50mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
929.	050206	Lamikacin Injection 250mg. Each 2ml vial contains: Amikacin as Sulphate……..250mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
930.	050207	Lamikacin Injection 100mg. Each 2ml vial contains: Amikacin as Sulphate.....100mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
931.	050208	Lawrkomycin Injection 500mg. Each 2ml vial contains: Kanamycin as Sulphate……..500mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
932.	050209	Lawrkomycin Injection 1gm. Each 4ml vial contains: Kanamycin as Sulphate……..1gm. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
933.	050210	Lawrcimid Injection. Each 2ml Ampoule contains: Cimetidine……200mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
934.	050211	Lawrgmycin Injection. Each 1ml Ampoule Contains: Gentamycin as Sulphate……40mg. (USP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
935.	050212	LeskopanInjeciton. Each 1ml contains: Hyoscine-N-Butyl bromide……20mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
936.	050213	Lawrbocin Injection 80mg.	24-07-2008	Dy. No. 25145		-do-

		Each 2ml vial contains: Tobramycin as Sulphate…….80mg. (BP Specs)		19-07-2018 10000/-		
937.	050214	Lawrbocin Injection 20mg. Each ml vial contains: Tobramycin as Sulphate……20mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
938.	050215	Lamikacin Injection 500mg. Each 2ml vial contains: Amikacin as Sulphate……500mg. (BP Specs)	24-07-2008	Dy. No. 25145 19-07-2018 10000/-		-do-
M/s. A. Z. Pharmaceutical Co. Ltd., 4-Km Manga Road, Raiwind, District Lahore.						
939.	014233	Immunasol 5% IV Infusion Each 1000ml Contains: Dextrose Anhydrous…50gm	05-08-1993	Dy. No. 23229 05-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 22-3-2019 which has not yet been responded by the firm.
940.	014234	Immunasol 10% IV Infusion Each 1000ml Contains: Dextrose Anhydrous…100gm	05-08-1993	Dy. No. 23229 05-07-2018 10000/-		-do-
941.	014235	Immunasol NS IV Infusion Each 1000ml Contains: Sodium Chloride…9gm	05-08-1993	Dy. No. 23229 05-07-2018 10000/-		-do-
942.	014236	Immunasol DN IV Infusion Each 1000ml Contains: Dextrose Anhydrous…50gm Sodium Chloride…9gm	05-08-1993	Dy. No. 23229 05-07-2018 10000/-		-do-
M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar NiazBaig, Multan Road, Lahore						
943.	014206	Uricol Syrup Each 5ml Contains: Sodium Acid Citrate…1.25g	20-07-1993	Dy. No. 24178 12-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 04-04-2019 which has not yet been responded by the firm.
944.	014207	Cobact Suspension Each 5ml Contains: Trimethoprim…40mg Sulphamethoxazole 200mg	20-07-1993	Dy. No. 24178 12-07-2018 10000/-		-do-
945.	037238	Fiterna Tablet Each Tablet contains: Vit A 6000iu	15-07-2008	Dy. No. 24180 12-07-2018 10000/-		-do-

		Vit D . . . . . .500iu Vit E . . . . 15mg B1 . . . . . 1.6mg B2 . .. . 1.8mg B6 . . . . . 2.6mg B12 . . . . 4mcg Nicotonamide . . . . 19mg Calcium pantothenate . . 10mg Biotin . . . . . 0.2mg Folic Acid . . . . . 0.8mg Calcium elemental . . . 125mgVit C . .. 100mg Iron elemental . . . . 60mg Phosphorus. . . . . 125mg Manganese elemental . 1mg Magnesium elemental .....100mg Copper elemental. . . 1mg Zinc elemental. . . . 7.5mg				
946.	037239	Englopt Tablets Each tablet contains: Vitamin A . . . . . 5000iu Vitamin B1 . . . . . 5mg Vitamin B2 . . . 3mg Vitamin B6. . . . . 5mg Vitamin B12. . . 3mcg Nicotinamide . 25mg DPanthenol . 10mg Biotin. . .. . . 50mcg Procaine Hcl . . 55mg Folic Acid . . . . 0.4mg Inositol . . . . . 30mg Orotic Acid .. . . 30mg Vitamin C . . . . 60mg Vitamin D . . . . . 400iu Vitamin E . . . . . 10mg Rutin . . . . . 20mg Ethyl Linolate . . 28mg Lecithin . . . . . 60mg Choline hydrogen tartrate . .50mg LLysine monohydrochloride . . 25mg Hematoporphyrin . 1mg Adenosine. . 75mg Intrinsic Factor... 6.25mg Magnesium Glycerophospha . . 40mg Dehydrated Calc . . 35mg Potassium Sulphate...8mg Dehydrated Ferous (ll) Sulphe . . 10mg Dehydrated Cupric (ll) Sulph . . 0.5mg Dehydrated Man . .0.5mg Dehydrated cobaltous (ll) St . . . 0.1mg Dehydrated Sodium Molybdc . . 80mcg	15-07-2008	Dy. No. 24180 12-07-2018 10000/-		-do-

		Zinc Oxide 0.5mg				
947.	037240	Iron (PS) Syrup Each 15 ml contains : Iron Protein Succinylate . . . 800mg (eq to iron 40mg)	15-07-2008	Dy. No. 24180 12-07-2018 10000/-		-do-
948.	037229	Zecol + Tablet Each Tablet Contains: Vitamin A...4000IU, Vitamin B1…2mg, Vitamin B2…2mg, Vitamin B6…1mg, Vitamin B12…1mcg, Ginseng Extract…40mg, Dimethyle aminoethanol Bitaratrate…26mg, Vitamin C…60mg, Zinc…1mg, Nicotinamide…15mg, Calcium Pantothenate…10mg, Rutine…20mg, Iron…10mg, Calcium…90.3mg, Phosphorus...70mg, Fluorine...0.2mg, Copper...1mg, Potassium...8mg, Manganese...1mg, Magnesium...10mg, Lecithin...66mg	15-07-2008 Change of brand name dated 18-5-2011.	Dy. No. 24180 12-07-2018 10000/-		-do-
949.	037230	Evival Tablet Each Tablet Contains: Vitamin A…700IU, Vitamin D…5mcg, Vitamin E…30mg, Vitamin C…120mg, Vitamin B1…15mg, Vitamin B2…5mg, Niacin…45mg, Vitamin B6…25mg, Vitamin B12…9mcg, Folic Acid…500mcg, Biotin…200mcg, Pantothenic Acid…10mg, Iron…8mg, Magnesium…100mg, Zinc…15mg, Manganese…12mg, Selenium...100mcg, Chromium...200mcg, Iodine...100mcg	15-07-2008	Dy. No. 24180 12-07-2018 10000/-		-do-
950.	037231	Vitaferol Injection Each Injection Contains: Cholecalciferol…200,000IU	15-07-2008 Change of brand name dated: 28-02-2017	Dy. No. 24180 12-07-2018 10000/-		-do-
951.	037232	Kedvet Syrup Each 80ml Contains: Magnesium Glutamate	15-07-2008	Dy. No. 24180 12-07-2018 10000/-		-do-

		Hydroboromide…2gm Gama-Amino-Butyric Acid…2gm Gama-Amino-Beta-Hydroxy-Butyric Acid…1gm Vitamin B6…1gm				
952.	037246	Englobi Tablet Each Capsule Contains: Ginseng Radix…100mg, Lecithin…9.5mg (P….0.29mg), Vitamin A Oil…2400IU, Thiamine HCl…2.5mg, Vit. B2…2.5mg, Vit.B6…1mg, Vit.B12…4.9mcg, Vit.C…40mg, Vit.D2…240 IU, Vit.E…2mg, Nicotinamide…20mg, Calcium Pantothenate….10mg, Anhydrous Dibasic Calcium Phosphate...100mg, (Ca...29.5mg P...22.8mg), Magnesium Oxide...100mg (Mg...6mg), Cupric Oxide...1mg (Cu...0.8mg), Manganese Sulfate...2mg (Mn...0.47), Zinc Oxide...5mg (Zn...4mg), Dried Ferrous Sulfate...33mg (Fe...10mg)	15-07-2008	Dy. No. 24180 12-07-2018 10000/-		-do-
953.	049472	Engbone Injection 1mcg. Each 0.5 ml contains: Alfacalcidol…….1mcg	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
954.	049473	Engbone Tablets 0.5mcg. Each Tablet contains: Alfacalcidol….0.5mcg.	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
955.	049474	Pantakure Tablets 40mg. Each enteric coated Tablet contains: Lansoprazole as Sodium Sesquihydrate…40mg.	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
956.	049475	Mewin Tablets 500mcg. Each Tablet contains: Mecobalamin…500mcg.	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
957.	049476	Celsef Capsule 500mg. Each Capsule contains: Cefadroxil…500mg. (USP)	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
958.	49477	Celsef Dry Suspension 125mg. Each 5ml contains: Cefadroxil…..125mg. (USP Specs)	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
959.	049478	Celsef Dry Suspension	15-07-2008	Dy. No. 24179		-do-

		250mg. Each 5ml contains: Cefadroxil…..250mg. (USP Specs)		12-07-2018 10000/-		
960.	049479	Zapris Capsule. Each capsule contains: Ziprasidone as HCl monohydrate……40mg.	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
961.	049480	Klavor 250mg Tablets. Each Tablet Contains: Clarithromycin…..250mg (USP Specs)	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
962.	049481	Klavor 500mg Tablets. Each Tablet Contains: Clarithromycin..500mg. (USP Specs)	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
963.	049482	Engoxin Tablets. Each Tablet contains: Roxithromycin…….150 mg.	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
964.	049483	Enzoxen Capsules 250mg. Each Capsule contains: Azithromycin…250mg. (USP Specs)	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
965.	049484	Zopiramate Tablets 25mg. Each Tablet contains: Topiramate……25 mg.	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
966.	049485	Zopiramate Tablets 50mg. Each Tablet contains: Topiramate……50mg	15-07-2008	Dy. No. 24179 12-07-2018 10000/-		-do-
M/s. Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI Industrial Estate, Rawat, Rawalpindi						
967.	001016-EX	Levise Tablet Each Film Coated Tablet Contains: Levocetirizine 2HCl ...5mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 13-3-2019 which has not yet been responded by the firm.
968.	001017-EX	Rumak Tablet Each Film Coated Tablet Contains: Diclofenac Potassium…75mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
969.	001018-EX	Lovin Tablet 250mg Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
970.	1019-EX	Lovin Tablet 500mg Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…500mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
971.	1021-EX	Ciprise 250mg Tablet	28-07-2008	Dy. No. 25928		-do-

		Each Film Coated Tablet Contains: Ciprofloxacin as HCl…250mg		27-07-2018 10000/-		
972.	1022-EX	Ciprise 500mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…500mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
973.	1023-EX	Wisest 20mg Capsule Each Capsule Contains: Esomeprazole Enteric Coated Pellets eq. to Esomeprazole…20mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
974.	1024-EX	Wisest 40mg Capsule Each Capsule Contains: Esomeprazole Enteric Coated Pellets eq. to Esomeprazole…40mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
975.	1026-EX	Wizol 20mg Capsule Each Capsule Contains: Omeprazole Enteric Coated Pellets eq. to Omeprazole…20mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
976.	1027-EX	Hexim 400mg Capsule Each Capsule Contains: Cefixime as (Trihydrate)…400mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
977.	1028-EX	Hexime Dry Suspension 100mg/5ml Each 5ml Contains: Cefixime as (Trihydrate)…100mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
978.	1029-EX	Hexime Dry Suspension 200mg/5ml Each 5ml Contains: Cefixime as (Trihydrate)…200mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
979.	1030-EX	Sofenac Capsule 500mg Each Capsule Contains: Cephradine as Monohydrate…500mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
980.	1031-EX	Sofenac Capsule 250mg Each Capsule Contains: Cephradine as Monohydrate…250mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
981.	1032-EX	Sofenac Dry Suspension 125mg/5ml Each 5ml Contains: Cephradine as Monohydrate…125mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
982.	1033-EX	Sofenac Dry Suspension 250mg/5ml Each 5ml Contains: Cephradine as Monohydrate…250mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
983.	1034-EX	Tarson Injection 250mg	28-07-2008	Dy. No. 25928		-do-

		Each vial contains: Ceftriaxone as Sodium…250mg		27-07-2018 10000/-		
984.	1035-EX	Tarson Injection 1gm Each vial contains: Ceftriaxone as Sodium…1gm	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
985.	1036-EX	Sefox Injection 1gm Each vial contains: Cefotaxime as Sodium…1gm	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
986.	1037-EX	Sefox Injection 250mg Each vial contains: Cefotaxime as Sodium…250mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-		-do-
M/s. Zumars Pharma FTY (Pvt) Ltd., 2-Malir Industrial Area, Malir, Karachi						
987.	48639	Colstral 10mg Tablets Each tablet contains: Simvastatin……10mg(USP Specification)	26-07-2008	Dy. No. 25762 24-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 21-3-2019 and 08-04-2019 which has not yet been responded by the firm.
988.	48638	Zumazar 10mg Tablets Each tablet contains: Atorvastatin (as Calcium Salt)….10mg)	26-07-2008	Dy. No. 25761 24-07-2018 10000/-		-do-
989.	49556	NEOCEF WATER SOLUBLE POWDER. Each 1000gm contains: CHLORTETRACYCLINE HYDROCHLORIDE 40GM. NEOMYCIN (AS SULPHATE)…. 12GM. FURALTADONE …30GM.	#N/A	Dy. No. 25760 24-07-2018 10000/-		-do-
990.	48641	Zurafenac 50mg Tablets EACH ENTERIC COATED TABLET CONTAINS: Diclofenac Sodium…..50mg(BP Specification)	26-07-2008	Dy. No. 25759 24-07-2018 10000/-		-do-
991.	48640	Zumaflam-P 50mg Tablets Each sugar coated tablet contains: Diclofenac Potassium…..50mg(BP Specification)	26-07-2008	Dy. No. 25757 24-07-2018 10000/-		
992.	48642	Umaroxin 250mg Tablets Each film coated tablet contains: Ciprofloxacin (as HCl)…..250mg(USP	26-07-2008	Dy. No. 25758 24-07-2018 10000/-		-do-

		Specification)				
993.	48643	Umaroxin 500mg Tablets Each film coated tablet contains: Ciprofloxacin (as HCl)…..500mg (USP Specification)	26-07-2008	Dy. No. 25756 24-07-2018 10000/-		-do-
M/s. Lisko Pakistan (Pvt) Ltd., L-10/D, Block-21, Federal-B Area, Karachi						
994.	009292	Sefalex Syrup Each 5ml Contains: Cephalexin Monohydrate eq. to Cephalexin…125mg	09-06-1988 12-06-1996	Dy. No. 24128 11-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 08-04-2019 and 08-04-2019 which has not yet been responded by the firm.
M/s. Crown Pharmaceuticals Islamabad, Plot No. 286, Industrial Triangle Kahuta Road, Islamabad						
995.	050284	Ciprown 500mg Tablets. Each Tablet Contains: Ciprofloxacin as HCl ……..500mg. (USP Specs)	28-07-2008	Dy. No. 25764 24-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 21-3-2019 which has not yet been responded by the firm.
996.	050278	Topiraid 50mg Tablets. Each Tablet Contains: Topiramate…….50 mg.	28-07-2008	Dy. No. 25773 24-07-2018 10000/-		-do-
997.	050283	Ciprown 250mg Tablets. Each Tablet Contains: Ciprofloxacin as HCl ..……250mg. (USP Specs)	28-07-2008	Dy. No. 25763 24-07-2018 10000/-		-do-
998.	050280	Levorown 500mg Tablets. Each Tablet Contains: Levofloxacin as Hemihydrate…500mg (USP Specs)	28-07-2008	Dy. No. 25766 24-07-2018 10000/-		-do-
999.	050282	Esorown 40mg Tablets. Each Tablet Contains: Esomeprazole…….40mg.	28-07-2008	Dy. No. 25768 24-07-2018 10000/-		-do-
1000.	050272	Piroxirown Tablets. Each Tablet Contains: Piroxicam ……..20mg	28-07-2008	Dy. No. 25772 24-07-2018 10000/-		-do-
1001.	050279	Levorown 250mg Tablets. Each Tablet Contains: Levofloxacin as Hemihydrate....250mg (USP Specs)	28-07-2008	Dy. No. 25765 dated 24-07-2018 10000/-		-do-
1002.	050269	Alfarown Tablets. Each Tablet Contains: Alfacalcidol……..0.5mcg	28-07-2008	Dy. No. 25770 24-07-2018 10000/-		-do-
1003.	050276	Rabirown 20mg Tablets.	28-07-2008	Dy. No. 25771		-do-

		Each Tablet Contains: Rabeprazole……20mg.		24-07-2018 10000/-		
1004.	050281	Esorown 20mg Tablets. Each Tablet Contains: Esomeprazole.....20mg.	28-07-2008	Dy. No. 25767 24-07-2018 10000/-		-do-
1005.	050274	Tizanic Tablets. Each Tablet Contains: Tizanidine HCl…..2mg. (USP Specs)	28-07-2008	Dy. No. 25774 24-07-2018 10000/-		-do-
1006.	050270	Paraxtil Tablets. Each Tablet Contains: Paroxetine……..20mg. (B.P Specs)	28-07-2008	Dy. No. 25775 24-07-2018 10000/-		
1007.	050268	Estarown Tablets. Each Tablet Contains: Escitalopram as Oxalate……10mg	28-07-2008	Dy. No. 25769 24-07-2018 10000/-		
M/s. Pharmacare Laboratories (Pvt) Ltd., 129/1, Industrial Estate, Kot Lakhpat, Lahore						
1008.	030289	Protofix Tablets Each tablet contains: Pantoprazole Sodium Sesquihydrate eq. to Pantoprazole…..40mg	07-07-2003	Dy. No. 23225 05-07-2018 10000/-		GMP report submitted is of 2013.
1009.	030340	Exmic-500 Tablets Each tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin…..500mg	07-07-2003	Dy. No. 23224 05-07-2018 10000/-		
1010.	030290	Cetahist Tablets Each tablet contains: Cetirizine 2HCl…..10mg	07-07-2003	Dy. No. 23223 05-07-2018 10000/-		
1011.	030339	Exmic-250 Tablets Each tablet contains: Levofloxacin Hemihydrate eq. to Levofloxacin…..250mg	07-07-2003	Dy. No. 23222 05-07-2018 10000/-		
1012.	030341	Citarid Tablets Each tablet contains: Citalopram HBr…..20mg	07-07-2003	Dy. No. 23221 05-07-2018 10000/-		
M/s. Lahore Pharma, 9-Km Sheikhupura Road, Lahore						
1013.	021657	Lpzine Cream Contains: Silver Sulphadiazine…1gm w/w	11-07-1998	Dy. No. 23683 09-07-2018 10000/-		Evidence of last renewal is not submitted
M/s. Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, ThokarNiazBaig, Multan Road, Lahore.						
1014.	50216	Kartilin Plus Tablet Each Tablet Contains: Glucosamine…500mg Chondroitin Sulphate…400	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 04-04-2019 which has not yet been responded by the firm.
1015.	50217	Kartilin Tablet Each Tablet Contains: Glucosamine…500mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-

1016.	50218	Frisil Tablet Each Tablet Contains: Magnesium Trisilicate…500mg Aluminium Hydroxide Gel…250mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1017.	50219	Chlorpheniramine Tablet Each Tablet Contains: Chlorpheniramine Maleate…4mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1018.	50220	Fersate Tablet Each Sugar Coated Tablet Contains: Ferrous Sulphate…200mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1019.	50221	Folistel Tablet Each Tablet Contains: Folic Acid…5mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1020.	50222	Festobal Tablet Each Sugar Coated Tablet Contains: Mecobalamin…500mcg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1021.	50223	Festahist Tablet Each Film Coated Tablet Contains: Loratidine…10mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1022.	50224	Festozin Tablet Each Film Coated Tablet Contains: Levocetirizine 2HCl …5mg	24-07-2008	Dy. No. 24508 16-07-2018 10000/-		-do-
1023.	74331	Sulpril 50mg Tablet Each tablet contains: Levosulpride….50mg	09-07-2013	Dy. No. 23219 05-07-2018 10000/-		-do-
M/s. Legacy Pharmaceuticals (Pvt) Limited, 111-A Industrial Estate Hayatabad, Peshawar						
1024.	50092	Lesozol 20mg Capsule Each Capsule Contains: Esomeprazole as Magnesium Trihydrate…20mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.
1025.	50093	Lesozol 40mg Capsule Each Capsule Contains: Esomeprazole as Magnesium Trihydrate…40mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-		-do-
1026.	50094	Ompecid Capsule 20mg Each Capsule Contains: Omeprazole Pellets…20mg	21-07-2008 Brand name change dated: 16-1-2014	Dy. No. 24171 12-07-2018 10000/-		-do-
1027.	50095	Ompecid Capsule 40mg Each Capsule Contains: Omeprazole Pellets…40mg	21-07-2008 Brand name change: 16-1-2014	Dy. No. 24171 12-07-2018 10000/-		-do-
1028.	50096	Lanso Capsule Each Capsule Contains:	21-07-2008	Dy. No. 24171 12-07-2018		-do-

		Lansoprazole…30mg		10000/-		
1029.	50097	Legofen Capsule Each Capsule Contains: Diclofenac Sodium Pellets…50mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-		-do-
1030.	49854	Urinac Tablet Each Tablet Contains: Norfloxacin…400mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1031.	49855	Legamox 400mg Tablet Each Tablet Contains: Moxifloxacin…400mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1032.	49856	Lepracit 10mg Tablet Each Tablet Contains: Escitalopram as Oxalate…10mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1033.	49857	Ribena-F Tablet Each Chewable Tablet Contains: Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron…100mg Folic Acid…0.35mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1034.	49858	Ciprate 20mg Tablet Each Film Coated Tablet Contains: Citalopram as HBr…20mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1035.	49859	Emitilium 10mg Tablet Each Tablet Contains: Domperidone…10mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1036.	49860	Napxen 250mg Tablet Each Film Coated Tablet Contains: Naproxen…250mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1037.	49861	Napxen 500mg Tablet Each Film Coated Tablet Contains: Naproxen…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1038.	49862	Acetamol 500mg Tablet Each Tablet Contains: Paracetamol…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1039.	49863	Acetamol Extra Tablet Each Tablet Contains: Paracetamol…500mg Caffeine…65mg Chlorpheniramine Maleate…2mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1040.	49864	Levobac 250mg Tablet Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1041.	49865	Levobac 500mg Tablet Each Film Coated Tablet Contains: Levofloxacin as Hemidydrate…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-

1042.	49866	Olax 200mg Tablet Each Film Coated Tablet Contains: Ofloxacin…200mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1043.	49867	Olax 400mg Tablet Each Film Coated Tablet Contains: Ofloxacin…400mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1044.	49868	Leganil 500mg Tablet Each Tablet Contains: Nalidixic Acid…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1045.	49869	Leganil 1000mg Tablet Each Tablet Contains: Nalidixic Acid…1000mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1046.	49870	Legocip 250mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…250mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1047.	49871	Legocip 500mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-		-do-
1048.	49872	Lexime 400mg Capsule Each Capsule Contains: Cefixime…400mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1049.	49873	Roxif 500mg Capsule Each Capsule Contains: Cefadroxil as Monohydrate…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1050.	49874	Fluzox 150mg Capsule Each Capsule Contains: Fluconazole…150mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1051.	49875	Depox 20mg Capsule Each Capsule Contains: Fluoxetine as HCl…20mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1052.	49876	Legicam 20mg Capsule Each Capsule Contains: Piroxicam…20mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1053.	49877	Legaceph 250mg Capsule Each Capsule Contains: Cephradine…250mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1054.	49878	Legaceph 500mg Capsule Each Capsule Contains: Cephradine…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1055.	49879	Efaclor 250mg Capsule Each Capsule Contains: Cefaclor…250mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1056.	49880	Efaclor 500mg Capsule Each Capsule Contains: Cefaclor…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1057.	49881	Lexina 250mg Capsule Each Capsule Contains: Cephalexin as Monohydrate…250mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1058.	49882	Lexina 500mg Capsule	16-07-2008	Dy. No. 24317		-do-

		Each Capsule Contains: Cephalexin as Monohydrate…500mg		12-07-2018 10000/-		
1059.	49883	Fusidax Cream Each gm Contains: Fusidic Acid…20mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1060.	49884	Fusidax-H Cream Each gm Contains: Fusidic Acid…20mg Hydrocortisone Acetate…10mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1061.	49885	Polybac Skin Ointment Each gm Contains: Polymyxin B Sulphate…10,000Units Bacitracin Zinc…500Units	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1062.	49886	Clozam Cream Each gm Contains: Clotrimazol…10%	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1063.	49887	Legicam Cream Each gm Contains: Piroxicam…0.5%	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1064.	49888	Hydrol ORS Sachet Each Sachet Contains: Sodium Chloride…2.6gm Trisodium Citrate Dihydrate…2.9gm Potassium Chloride…1.5gm Dextrose Anhydrous…13.05gm	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1065.	49889	Airin Syrup Each 5ml Contains: Salbutamol as Sulphate…2mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-		-do-
1066.	49890	Doxip Dry Suspension Each 5ml Contains: Cefpodoxime as Proxetil…40mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1067.	49891	Leganil Suspension Each 5ml Contains: Nalidixic Acid…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1068.	49892	Leriton Syrup Each 5ml Contains: Chlorpheniramine Maleate…2mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1069.	49893	Acetamol Suspension Each 5ml Contains: Paracetamol…120mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1070.	49894	Metrol Suspension Each 5ml Contains: Metronidazole as Benzoate…200mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1071.	49895	Lexime Dry Suspension Each 5ml Contains: Cefixime…100mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-

1072.	49896	Emitilium Suspension Each ml Contains: Domperidone…1mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1073.	49897	Roxif 125mg Dry Suspension Each 5ml Contains: Cefadroxil as Monohydrate…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1074.	49898	Roxif 250mg Dry Suspension Each 5ml Contains: Cefadroxil as Monohydrate…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1075.	49899	Legaceph 125mg Dry Suspension Each 5ml Contains: Cephradine…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1076.	49900	Legaceph 250mg Dry Suspension Each 5ml Contains: Cephradine…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1077.	49901	Laxina 125mg Dry Suspension Each 5ml Contains: Cephalexin as Monohydrate…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1078.	49902	Laxina 250mg Dry Suspension Each 5ml Contains: Cephalexin as Monohydrate…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1079.	49903	Efaclor 125 Dry Suspension Each 5ml Contains: Cefaclor…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1080.	49904	Efaclor 250 Dry Suspension Each 5ml Contains: Cefaclor…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1081.	49905	Cofnol-E Syrup Each 5ml Contains: Aminophylline…32mg Diphenhydramine HCl…8mg Ammonium Chloride…30mg Menthol…0.98mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1082.	49906	Montekast Sachet Each Sachet Contains: Montelukast as Sodium…4.0mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1083.	49907	Noscab Cream Contains: Lindane…1%	16-07-2008	Dy. No. 24318 12-07-2018 10000/-		-do-
1084.	49908	Skinazin Cream Contains: Silver Sulphadiazine ..1%	16-07-2008	Dy. No. 24319 12-07-2018 10000/-		-do-

1085.	49909	Remistate Cream Contains: Miconazole Nitrate…2%	16-07-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1086.	50098	Legofen-P Capsule Each Capsule Contains: Diclofenac Potassium Pellets…50mg	21-07-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1087.	52832	Hireez 10mg Tablet Each Film Coated Tablet Contains: Cetirizine 2HCl…10mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1088.	52833	Legofen Gel Each 100gm Contains: Diclofenac as Diethyl Ammonium Salt…1gm	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1089.	52834	Hireez Syrup Each ml Contains: Cetirizine 2HCl…1mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1090.	52835	Ribena-F Syrup Each 5ml Contains: Iron-III Hydroxide Polymaltose Complex eq. to Elemental Iron…50mg Folic Acid…0.35mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1091.	52836	Lebon Sachet Each Sachet Contains: Calcium Lactate Gluconate…3.24g Calcium Carbonate…0.30g	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1092.	52837	Ener-Cee Sachet Each Sachet Contains: Calcium Lactate Gluconate…1000mg Vitamin C…500mg Calcium Carbonate…327mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1093.	52838	Remistate-HC Cream Each Tube Contains: Miconazole Nitrate…2% Hydrocortisone…1%	20-11-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1094.	53622	Spasmorin Tablet Each Tablet Contains: Mebeverine as HCl…135mg	04-12-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
1095.	53623	Ascorbic-500 Sachet Each Sachet Contains: Vitamin C…500mg	04-12-2008	Dy. No. 24319 12-07-2018 10000/-		-do-
M/s. Hansel Pharmaceuticals (Pvt) Ltd., Plot No. 2, Pharma City, 30-Km Multan Road, Lahore						
1096.	50132	Antimal Tablet Each Large Tablet Contains: Sulfadoxine…500mg Pyriemthamine…25mg Each Small Tablet Contains: Artesunate…50mg	22-07-2008	Dy. No. 23892 10-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.

1097.	50133	Mebandasel Tablet Each Tablet Contains: Mebendazole…100mg	22-07-2008	Dy. No. 23892 10-07-2018 10000/-		-do-
1098.	50134	Antimal-Forte Tablet Each Large Tablet Contains: Sulfadoxine…500mg Pyriemthamine…25mg Each Small Tablet Contains: Artesunate…100mg	22-07-2008	Dy. No. 23892 10-07-2018 10000/-		-do-
1099.	50135	Artimet Tablet Each Film Coated Tablet Contains: Artemether…20mg Lumefantrine…120mg	22-07-2008	Dy. No. 23892 10-07-2018 10000/-		-do-
M/s. Vega Pharmaceuticals (Pvt) Ltd., 30-Km Multan Road, Lahore						
1100.	43446	Difsom Gel Each gm Contains: Diclofenac Diethylammonium eq. to Diclofenac Sodium…10mg	15-09-2008	Dy. No. 23890 10-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.
M/s. Otsuka Pakistan Ltd., F/4-9, Hub Industrial Trading Estate, Distt. Lasbella, Balochistan						
1101.	22318	Pan-Amin SG Injection Each 100ml Contains: D-Sorbitol…5gm L-Arginine HCl…0.8gm L-Histidine HCl…0.4gm L-Isoleucine…0.55gm L-Leucine…1.23gm L-Lysine HCl…1.86gm L-Methionine…0.71gm L-Phenylalanine…0.87gm L-Threonine…0.54gm L-Tryptophan…0.18gm L-Valine…0.61gm Glycine (Amino Acetic Acid)…1gm Water for Injection qs	17-11-1998	Dy. No. 25221 19-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 12-04-2019 which has not yet been responded by the firm.
1102.	31125	Neodexsal Injection Each 1000ml Contains: Dextrose Monohydrate…100gm Sodium Chloride…1.8gm Water for Injection qs to make 1000ml	03-12-2003	Dy. No. 25223 19-07-2018 10000/-		-do-
1103.	31126	Plabolyte-40 Injection Each 1000ml Contains: Dextrose Monohydrate…50gm Potassium Chloride…3gm Water for Injection qs to make 1000ml	03-12-2003	Dy. No. 25222 19-07-2018 10000/-		-do-

M/s. Akhai Pharmaceuticals (Pvt) Ltd., A-248, A-256 to A-259, H.I.T.E., Lasbela, Baluchistan						
1104.	75995	Sulpy 100mg Tablet Each Tablet Contains: Levosulpiride…100mg	19-09-2013	Dy. No. 23889 10-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 12-04-2019 which has not yet been responded by the firm.
1105.	75996	Togal 200mg Tablet Each Tablet Contains: Quetiapine as Fumarate…200mg	19-09-2013	Dy. No. 23888 10-07-2018 10000/-		-do-
M/s. Saffron Pharmaceuticals (Pvt) Ltd., 19-Km Sheikhupura Road, Faisalabad						
1106.	52953	Locus 500mg/100ml Infusion Each 100ml Vial Contains: Levofloxacin (as Hemihydrate)…500mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-04-2019 which has not yet been responded by the firm.
1107.	52954	Doplet-3 5mg/ml Injection Each ml Contains: Cholecalciferol…5mg	28-11-2008 Change of brand name dated: 26-07-2011	Dy.# 25139 19-07-2018 10000/-		-do-
1108.	52955	Cetrix 5mg/5ml Syrup Each 5ml Contains: Cetirizine Dihydrochloride…5mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1109.	52958	Terbisil 250mg Tablet Each Tablet Contains: Terbinafine (as HCl)…250mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1110.	52959	Provate 0.05% w/w Cream Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1111.	52961	Provate 0.05% w/w Ointment Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1112.	52962	Cosmin 0.05% w/w Gel Each gm Contains: Isotretinoin…0.50mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1113.	52963	Provate-G Cream Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg Gentamycin Sulphate…1.00mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-

1114.	52964	Provate-S Ointment Each gm Contains: Betamethasone (as Dipropionate)…0.50mg Salicylic Acid…30mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1115.	52965	Provate Lotion Each ml Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1116.	52966	Provate-G Ointment Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg Gentamycin Sulphate…1.00mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1117.	52968	Water for Injection 5ml Ampoule Each Injection Contains: Water for Injection…5ml	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1118.	52969	Noctis 20mg Capsule Each Capsule Contains: Omeprazole (Omeprazole Pellets)…20mg	28-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1119.	52988	Gatron Injection Each ml Contains: Granisetron (as HCl)…1.0mg	29-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1120.	52990	Amorob 500mg/100ml Injection Each 100ml Vial Contains: Metronidazole…500mg	29-11-2008	Dy.# 25139 19-07-2018 10000/-		-do-
1121.	77026	Noctis 40mg Capsule Each Capsule Contains: Omeprazole (Pellets)…40mg	19-11-2013	Dy.# 25139 19-07-2018 10000/-		-do-
M/s. Regent Laboratories, C-20 S.I.T.E., Super Highway, Karachi						
1122.	4252	VITAMIN B COMPLEX TAB EACH TABLET CONTAINS: THIAMINE HCL 1MG, RIBOFLAVIN 1MG, NICOTINAMIDE 15MG,	13-07-1978	Dy.#24075 11-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.
1123.	4253	SULPHADIMIDINE TAB EACH TABLET CONTAINS: SULPHADIMIDINE 500MG,	13-07-1978	Dy.#24075 11-07-2018 10000/-		-do-
1124.	4254	MULTIVITAMIN SYP Contains: VITAMIN A 14000 1UVITAMIN D 400 1UTHIAMINE HCL 2.8MG, RIBOFLAVINE 3.4MG, NICTINAMODE 28.4MG, ASCORBIC ACID 85.2MG,	13-07-1978	Dy.#24075 11-07-2018 10000/-		-do-

1125.	4255	BISACODYL TAB EACH TABLET CONTAINS: BISACODYL 5MG,	13-07-1978	Dy.#24075 11-07-2018 10000/-		-do-
1126.	4256	PARACETAMOL COMPOUND TAB EACH TABLET CONTAINS: PARACETAMOL 200MG, ASPIRIN 300MG,	13-07-1978	Dy.#24075 11-07-2018 10000/-		-do-
M/s. Ahsons Drug Company, T/1, S.I.T.E., Tando Adam, Sindh						
1127.	3865	Multivitamin Syrup Each 5ml Contains: Nicotinamide…5mg, Vitamin A…2465Units, Thiamine HCl…0.493mg, Vitamin D…246, Riboflavin 5 Phos. Sod. …0.600mg, Ascorbic Acid…15mg	13-07-1978	Dy.#23319 05-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.
1128.	3864	ACRIFLAVIN NEUTRAL OINTMENT Each gm Contains: ACRIFLAVIN NEUTRAL 0.1%,	13-07-1978	Dy.# 23317 05-07-2018 10000/-		-do-
1129.	3866	METHYL SALICYLATE COMP. BALM Each gm Contains: METHYLSALICYLATE 12.17%, MENTHOL 2.6%, THYMOL 0.11%, OIL EUCALYPTUS 9.11%,	13-07-1978	Dy.#23316 05-07-2018 10000/-		-do-
1130.	3867	PARACETAMOL ELIXIR Contains: PARACETAMOL 120MG,	13-07-1978	Dy.# 23318 05-07-2018 10000/-		-do-
1131.	3868	VITAMIN B COMPOUND SYP Each 5ml Contains: Nicotinamide…7.66mg, Thiamine HCl…1mg, Riboflavin 5Phos. Sod. …1mg, Pyridoxine HCl…0.666mg	13-07-1978	Dy.#23320 05-07-2018 10000/-		-do-
1132.	30937	Cal-VC 1000 Tablet Each Tablet Contains: Calcium Lactate Gluconate…1000mg Ascorbic Acid…500mg Calcium Carbonate…327mg	07-08-2003	Dy.#25637 24-07-2018 10000/-		-do-
M/s. Swiss Pharmaceuticals (Pvt) Ltd, A/159, S.I.T.E., Super Highway, Karachi						
	75994	Sanamidol 40mg Capsule Each Capsule Contains: Omeprazole Enteric Coated Pellets eq. to Omeprazole…40mg	28-08-2013	Dy.#22797 02-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet

						been responded by the firm.
1133.	76071	Glumet 1gm Tablet Each Film Coated Tablet Contains: Metformin HCl…1000mg	20-09-2013	Dy. No. 22803 dated 02-07-2018 10000/-		-do-
1134.	76070	Glumet 850mg Tablet Each Film Coated Tablet Contains: Metformin HCl…850mg	20-09-2013	Dy. No. 22802 dated 02-07-2018 10000/-		-do-
1135.	76067	Mecomide 5mg/5ml Syrup Each 5ml Contains: Metoclopramide HCl…5mg	20-09-2013	Dy. No. 22799 dated 02-07-2018 10000/-		-do-
1136.	76068	Mecomide 10mg Tablet Each Tablet Contains: Metoclopramide HCl…10mg	20-09-2013	Dy. No. 22800 dated 02-07-2018 10000/-		-do-
1137.	76069	Glumet 250mg Tablet Each Film Coated Tablet Contains: Metformin HCl…250mg	20-09-2013	Dy. No. 22801 dated 02-07-2018 10000/-		-do-
1138.	18258	Lincomycin Capsule Each Capsule Contains: Lincomycin HCl eq. to Lincomycin…500mg	Nil	Dy. No. 22798 dated 02-07-2018 10000/-		-do-
M/s. Novartis Pharma (Pakistan) Ltd, 15 West Wharf, Dockyard Road, Karachi						
1139.	22200	Azomax 250mg Capsule Each Capsule Contains: Azithromycin…250mg	06-08-1998	Dy. No. 25302 dated 20-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 09-04-2019 which has not yet been responded by the firm.
1140.	22201	Azomax 200mg Oral Suspension Each 5ml Contains: Azithromycin…200mg	06-08-1998	Dy. No. 25301 dated 20-07-2018 10000/-		-do-
1141.	47670	Tamoxifen-Sandoz 10mg Tablet Each Film Coated Tablet Contains: Tamoxifen…10mg	04-08-2008	Dy. No. 25304 dated 20-07-2018 20000/-		-do-
1142.	47671	Tamoxifen-Sandoz 20mg Tablet Each Film Coated Tablet Contains: Tamoxifen…20mg	04-08-2008	Dy. No. 25303 dated 20-07-2018 20000/-		-do-
1143.	52235	Lozal 40mg Powder for Infusion Each Vial of Powder for Solution for Infusion Contains: Omeprazole Sodium eq. to 40mg Omeprazole	22-10-2008	Dy. No. 25305 dated 20-07-2018 20000/-		-do-
1144.	48831	Risperidone-Sandoz 1mg Tablet	22-07-2008	Dy. No. 23228 dated 05-07-2018		-do-

		Each film coated tablet contains: Risperidone…….1mg		10000/-		
1145.	48832	Risperidone-Sandoz 2mg Tablet Each film coated tablet contains: Risperidone…….2mg	22-07-2008	Dy. No. 23228 dated 05-07-2018 10000/-		-do-
1146.	48833	Risperidone-Sandoz 3mg Tablet Each film coated tablet contains: Risperidone…….3mg	22-07-2008	Dy. No. 23228 dated 05-07-2018 10000/-		-do-
1147.	48834	Risperidone-Sandoz 4mg Tablet Each film coated tablet contains: Risperidone…….4mg	22-07-2008	Dy. No. 23228 dated 05-07-2018 10000/-		-do-
M/s. Pearl Pharmaceuticals, Plot No. 204, Street No. 1, I-10/3 Industrial Area, Islamabad.						
1148.	051121	Claribest Tablets 250mg Each tablet contains: Clarithromycin…….250mg (USP Specs)	23-08-2008	Dy.# 23226 05-07-2018 10000/-		Letter of shortcomings issued to firm vide letter No.F.1-65/ 2018 (RRR) dated 08-04-2019 which has not yet been responded by firm.
1149.	051122	Claribest Tablets 500mg. Each tablet contains: Clarithromycin….500mg (USP Specs)	23-08-2008	Dy.# 23226 05-07-2018 10000/-		-do-
M/s. Lisko Pakistan (Pvt) Ltd., L-10/D, Block-21, Federal-B Area, Karachi						
1150.	009292	Sefalex Syrup Each 5ml Contains: Cephalexin Monohydrate eq. to Cephalexin…125mg	09-06-1988	Dy. No. 24128 dated 11-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 08-04-2019 which has not yet been responded by the firm.
M/s. Epla Laboratories (Pvt) Ltd., D-12, Estate Avenue, S.I.T.E., Karachi						
1151.	050359	Esgerd 40mg Capsule Each capsules contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate)…40mg Source: M/s Inventia Healthcare Pvt Limited, F1-F1/1, additional Ambernath M.I.D.C Ambernath (East) 421 506, Distt Thane Maharashtra State India.	04-08-2008	Dy.# 25927 27-07-2018 10000/-		Differential fee for the year 2013 is required.
1152.	050358	Esgerd 20mg Capsule Each capsules contains: Esomeprazole enteric coated	04-08-2008	Dy.# 25927 27-07-2018 10000/-		-do-

		pellets (as Magnesium Trihydrate)….20mg Source: M/s Inventia Healthcare Pvt Limited, F1-F1/1, additional Ambernath M.I.D.C Ambernath (East) 421 506, Distt Thane Maharashtra State India.				
M/s. Frontier Dextrose Ltd., Plot No. 18/3, Phase-I, Hattar Industrial Estate, Haripur						
1153.	049285	Sterifluid-DS 1/2 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose…5gm Sodium Chloride…0.45gm	09-07-2008	Dy.#23685 09-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 08-04-2019 and 08-04-2019 which has not yet been responded by the firm.
1154.	049286	Sterifluid-Pead's Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose…4.3gm Sodium Chloride…0.18gm	09-07-2008	Dy.#23685 09-07-2018 10000/-		-do-
1155.	049818	Sterifluid-5 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose …..……5gm. (B.P Specs)	16-07-2008	Dy.# 24515 16-07-2018 10000/-		-do-
1156.	049819	Sterifluid-10 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose …..…….……10gm. (B.P Specs)	16-07-2008	Dy.# 24515 16-07-2018 10000/-		-do-
M/s. Cherwel Pharmaceuticals (Pvt) Ltd., Plot No. 20, Phase 4, Hattar Industrial Estate, Hattar						
1157.	49490	Cherofex Tablets 60mg Each Tablet contains: Fexofenadine USP……60mg.	15-07-2008	Dy. No. 24181 dated 12-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 08-04-2019 which has not yet been responded by the firm.
1158.	49489	Cipwel Tablet 250mg Each film coated Tablet contains: Ciprofloxacin as HCl USP……250mg. (USP Specs)	15-07-2008	Dy. No. 24182 dated 12-07-2018 10000/-		-do-
1159.	49487	Execc Tablets 10mg Each film coated Tablet contains: Escitalopram as Oxalate……10mg.	15-07-2008	Dy. No. 24183 dated 12-07-2018 10000/-		-do-

1160.	051068	Chergab Capsules 300mg Each Capsule contains: Gabapentin……..300mg.	20-08-2008	Dy. No. 24184 dated 12-07-2018 10000/-		-do-
1161.	049491	Myzan 2mg Tablet Each Tablet contains: Tizanidine USP…….2mg. (USP Specs)	15-07-2008	Dy. No. 24185 dated 12-07-2018 10000/-		-do-
1162.	050806	Ferwel Tablets Each tablet contains: Iron III Hydroxypolymaltose complex eq. to elemental Iron …….100mg. Folic Acid ……0.35mg.	29-07-2008	Dy. No. 24186 dated 12-07-2018 10000/-		-do-
1163.	049488	Kerwel Tablets Each film coated Tablet contains: Diclofenac Potassium USP……50mg. (USP Specs)	15-07-2008	Dy. No. 24187 dated 12-07-2018 10000/-		-do-
M/s. Novins International (Pvt) Ltd., E-37-38, Port Bin Qasim Authority, Karachi						
1164.	48837	PGMin Tablet Each Film Coated Tablet Contains: Pioglitazone (as HCl)…15mg Metformin (as HCl)…500mg	22-07-2008	Dy. No. 23894 dated 10-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-04-2019 which has not yet been responded by the firm.
1165.	48838	NoviCip 250mg Tablet Each Tablet Contains: Ciprofloxacin (as HCl)…250mg	22-07-2008	Dy. No. 23895 dated 10-07-2018 10000/-		-do-
1166.	48839	NoviCip 500mg Tablet Each Tablet Contains: Ciprofloxacin (as HCl)…500mg	22-07-2008	Dy. No. 23896 dated 10-07-2018 10000/-		-do-
1167.	48840	Loxiwell 250mg Tablet Each Tablet Contains: Levofloxacin (as Hemihydrate)…250mg	22-07-2008	Dy. No. 23897 dated 10-07-2018 10000/-		-do-
1168.	48841	Loxiwell 500mg Tablet Each Tablet Contains: Levofloxacin (as Hemidydrate)…500mg	22-07-2008	Dy. No. 23898 dated 10-07-2018 10000/-		-do-
M/s. Maple Pharmaceutical (Pvt) Ltd., Plot#147, Sector 23, Korangi Industrial Area, Karachi.						
1169.	48788	Adgab 100mg Capsule Each Capsule Contains: Gabapentin…100mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-04-2019 which has not yet been responded by the firm.
1170.	48789	Acelo 100mg Tablet Each Tablet Contains: Aceclofenaac…100mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-

1171.	48790	Olisa 5mg Tablet Each Tablet Contains: Olanzapine…5mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1172.	48791	Olisa 10mg Tablet Each Tablet Contains: Olanzapine…10mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1173.	48792	Gemap 320mg Tablet Each Tablet Contains: Gemifloxacin (as Mesylate)…320mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1174.	48793	Glibetic Tablet Each Tablet Contains: Pioglitazone…15mg Glimepiride…2mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1175.	48794	Levolife 250mg Tablet Each Tablet Contains: Levofloxacin (as Hemihydrate)…250mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1176.	48795	Levolife 500mg Tablet Each Tablet Contains: Levofloxacin (as Hemihydrate)…500mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1177.	48796	Levolife 750mg Tablet Each Tablet Contains: Levofloxacin (as Hemihydrate)…750mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1178.	48797	Megab 75mg Capsule Each Capsule Contains: Pregabalin…75mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1179.	48798	Megab 150mg Capsule Each Capsule Contains: Pregabalin…150mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
1180.	48799	Megab 300mg Capsule Each Capsule Contains: Pregabalin…300mg	19-07-2008	Dy.#25026 18-07-2018 10000/-		-do-
M/s. Elko Organisation (Pvt) Ltd., 27&28, Sector 12/B, North Karachi Industrial Area, Karachi						
1181.	6065	LINCOMYCIN 600MG INJ Contains: LINCOMYCIN HCL 600MG,	-	Dy.#24176 12-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-03-2019 which has not yet been responded by the firm.
1182.	14274	Elkogent Injection Each 2ml Contains: Gentamicin Sulphate eq. to 80mg Gentamicin Base	25-07-1993	Dy.#24176 12-07-2018 10000/-		-do-
M/s. Bio-labs (Pvt) Ltd, Plot No. 145 Kahuta Triangle Industrial Estate, Islamabad.						
1183.	52570	Leptic tablets 200mg Each tablet contains: Carbamazepine …..200mg (USP Specs)	24-09-2008	Dy.# 24514 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-04-2019 which has not yet

						been responded by the firm.
1184.	52571	Glicala Tablets 80mg Each tablet contains: Gliclazide…….80mg (B.P Specs)	24-09-2008	Dy.# 24514 16-07-2018 10000/-		-do-
1185.	52572	Bidop Tablets Each tablet contains: Carbidopa as monohydrates…….25mg Levodopa ……250mg (USP Specs)	24-09-2008	Dy.# 24514 16-07-2018 10000/-		-do-
1186.	29673	Kerry Quine 20 Liquid Each ml Contains: Flumequine…200mg	22-09-2003	Dy. No. 23891 dated 10-07-2018 10000/-		-do-
1187.	29674	Kerry Flush Water Soluble Powder Each 100gm Contains: Methenamine…90gm Vitamin B1…700mg Vitamin C…100mg Sorbitol…5000mg	22-09-2003	Dy. No. 23891 dated 10-07-2018 10000/-		-do-
1188.	29675	Kerry ADEK Water Soluble Powder Each kg Contains: Vitamin A…20MIU Vitamin D3…2MIU Vitamin E…6000mg Vitamin K3…5000mg	22-09-2003	Dy. No. 23891 dated 10-07-2018 10000/-		-do-
M/s. GlaxoSmithKline Pakistan Limited, Plot No. 5, Sector 21, Korangi Industrial Area, Karachi						
1189.	21770	Calpol Plus Tablet Each Tablet Contains: Paracetamol…500mg Caffeine…65mg	20-05-1998 30-08-2003	Dy. No. 25292 dated 20-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 06-05-2019 which has not yet been responded by the firm.
1190.	012427	Calpol 6 Plus Suspension Each 5ml Contains: Paracetamol…250mg	14-03-1991	Dy. No. 25292 dated 20-07-2018 10000/-		-do-
1191.	000354	Calpol Suspension Each 5ml Contains: Paracetamol…120mg	17-04-1976	Dy. No. 25292 dated 20-07-2018 10000/-		-do-
1192.	001612	Calpol Tablet Each Tablet Contains: Paracetamol…500mg	15-08-1976	Dy. No. 25292 dated 20-07-2018 10000/-		-do-
1193.	003375	Ceporex Capsule 250mg Each Capsule Contains: Cephalexin Anhydrous (as Cephalexin)…250mg	04-01-1978	Dy. No. 25296 dated 20-07-2018 10000/-		-do-
1194.	005641	Ceporex Capsule 500mg Each Capsule Contains: Cephalexin Anhydrous (as Cephalexin)…500mg	16-11-1980	Dy. No. 25296 dated 20-07-2018 10000/-		-do-

1195.	010806	CeporexPaediatric Drops Each 1.25ml Contains: Cephalexin…125mg	24-03-1990	Dy. No. 25296 dated 20-07-2018 10000/-		-do-
1196.	003374	Ceporex Syrup 125mg/5ml Each 5ml Contains: Cephalexin Anhydrous (as Cephalexin)…125mg	04-01-1978	Dy. No. 25296 dated 20-07-2018 10000/-		-do-
1197.	006408	Ceporex Syrup 250mg/5ml Each 5ml Contains: Cephalexin Anhydrous (as Cephalexin)…250mg	07-08-1982	Dy. No. 25296 dated 20-07-2018 10000/-		-do-
1198.	000060	Furacin Cream Contains: Nitrofurazone in Water-Soluble Base…0.2%w/w	22-03-1976	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1199.	000068	Furadantin Tablet Each Tablet Contains: Nitrofurantoin…100mg	22-03-1976	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1200.	001608	Lanoxin Injection Each 2ml Ampoul Contains: Digoxin…0.5mg	15-08-1976	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1201.	000365	Lidosporin Ear Drops Each ml Contains: Polymyxin B Sulphate…10,000IU Lignocaine HCl…50mg Propylene Glycol…0.92ml	17-04-1976	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1202.	000370	Otosporin Ear Drops Each ml Contains: Polymyxin B Sulphate…10,000IU Neomycin Sulphate…3,400Units Hydrocortisone Acetate…10mg	17-04-1976	Dy. No. 25291 dated 20-07-2018 10000/-		-do-
1203.	003100	Dermovate Cream Contains: Clobetasol Propionate…0.05%w/w	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1204.	006230	Dermovate NN Ointment Contains: Clobetasol Propionate…0.05%w/w Neomycin Sulphate…0.5%w/w Nystatin.100,000 Units per gm	16-03-1982	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1205.	003139	Dermovate Ointment Contains: Clobetasol Propionate…0.05%w/w	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-		-do-
1206.	008382	Marzine Syrup Each 5ml Contains: Cyclizine HCl…12.5mg	18-06-1985	Dy. No. 25293 dated 20-07-2018 10000/-		-do-
1207.	000179	Maxolon Syrup Each 5ml Contains: Metoclopramide HCl eq. to Anhydrous Sustance…5mg	16-04-1976	Dy. No. 25293 dated 20-07-2018 10000/-		-do-

1208.	089275	Maxolon Injection Each 2ml Contains: Metoclopramide…10mg	28-08-1977	Dy. No. 25293 dated 20-07-2018 10000/-		-do-
1209.	000219	Orbanin Syrup Each 5ml Contains: Cloxacillin as Cloxacillin Sodium…125mg	16-04-1976	Dy. No. 25293 dated 20-07-2018 10000/-		-do-
1210.	000401	FefolSpansule Capsule Each Spansule Capsule Contains: Exsiccated Ferrous Sulphate…150mg Folic Acid…0.5mg	24-03-1976	Dy. No. 25294 dated 20-07-2018 10000/-		-do-
1211.	000402	Feospen Z Spansule Capsule Each Capsule Contains: Exsiccated Ferrous Sulphate…150mg Zinc Sulphate Monohydrate…61.8mg	22-03-1976	Dy. No. 25294 dated 20-07-2018 10000/-		-do-
1212.	20543	Fefol Z Spansule Pellets Each Capsule Contains: Dried Ferrous Sulphate…150mg Zinc Sulphate Monohydrate (eq. to 22.5mg Elemental Zinc)…61.8mg Folic Acid…0.5mg	12-11-1997	Dy. No. 25294 dated 20-07-2018 10000/-		-do-
1213.	013321	Nemazole Suspension Each 5ml Contains: Mebendazole…100mg	25-05-1992	Dy. No. 25299 dated 20-07-2018 10000/-		-do-
1214.	013320	Nemazole Tablet Each Tablet Contains: Mebendazole…100mg	25-05-1992	Dy. No. 25299 dated 20-07-2018 10000/-		-do-
1215.	017306	Nemazole-500 Chewable Tablet Each Tablet Contains: Mebendazole…500mg	21-06-1995	Dy. No. 25299 dated 20-07-2018 10000/-		-do-
1216.	000355	Cicatrin Powder Each gm Contains: Neomycin Sulphate…3300 Units Bacitracin Zinc…250 Units	17-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-		-do-
1217.	000357	Cortisporin Eye Ointment Each gm Contains: Polymyxin B Sulphate…5000 Units Bacitracin Zinc…400 Units Neomycin Sulphate…3400 Units Hydrocortisone…10mg	17-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-		-do-
1218.	000301	Cytacon Liquid Each 5ml Contains: Cynocobalamin…25mcg	20-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-		-do-
1219.	015819	Fortum Injection 250mg Each Vial Contains: Ceftazidime as Ceftazidime Pentahydrate…250mg	20-09-1994	Dy. No. 25297 dated 20-07-2018 10000/-		-do-

1220.	010078	Fortum Injection 500mg Each Vial Contains: Ceftazidime as Ceftazidime Pentahydrate…500mg	30-09-1990	Dy. No. 25297 dated 20-07-2018 10000/-		-do-
1221.	010077	Fortum Injection 1gm Each Vial Contains: Ceftazidime as Ceftazidime Pentahydrate…1gm	25-07-1990	Dy. No. 25297 dated 20-07-2018 10000/-		-do-
M/s. Karachi Pharmaceutical Laboratories, S/54, Hawkes Bay Road, S.I.T.E., Karachi						
1222.	50681	Acepril Tablet Each tablet contains: Captopril……...50mg Hydrochlorothiazide..…25mg	20-09-2008	Dy. No. 26016 dated 27-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 08-04-2019 which has not yet been responded by the firm.
1223.	50680	Pyrocam 20mg Capsule Each capsule contains: Piroxicam…..... .20mg	20-09-2008	Dy. No. 26015 dated 27-07-2018 10000/-		-do-
1224.	9930	Ministal Tablet 250mg EACH TABLET CONTAINS: MEFENAMIC ACID 250MG	15-09-1988 01-05-1990	Dy. No. 26017 dated 27-07-2018 10000/-		-do-
M/s. MeDLey Pharmaceuticals, 41-A, P.S.I.E. JhangBahtar Road, WahCantt. Rawalpindi						
1225.	075453	Le-Ride 100mg Capsule Each Capsule Contains: Levosulpiride….100mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		The firm submitted that due date was on Sunday and fee was submitted on Saturday, however application was submitted on Monday i.e. 23-07-2018. Latest GMP report is not submitted. Valid DML is not submitted.
1226.	075454	Arte-M Capsule 20/120 Each Capsule Contains: Artemether…20mg Lumefantrine…120mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1227.	075455	Arte-M Capsule 40/240 Each Capsule Contains: Artemether…40mg Lumefantrine…240mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1228.	075456	Z-Cin 250mg Capsule Each Capsule Contains: Azithromycin Dihydrate…250mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1229.	075457	Mexo120mg Capsule Each Capsule Contains: Fexofenadine…120mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1230.	075458	MecoCap 500mcg Capsule Each Capsule Contains:	22-07-2013	Dy. No. 25587 dated 23-07-2018		-do-

		Mecobalamin…500mcg		10000/-		
1231.	075459	Meroxi 20mg Capsule Each Capsule Contains: Piroxicam as Beta-Cyclodextrin…20mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1232.	075460	Medifos 500mg Capsule Each Capsule Contains: Fosfomycin Calcium eq. to Fosfomycin…500mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1233.	075461	Maltoley Syrup Each ml Contains: Iron III Hydroxide Polymaltose Complex..100mg Folic Acid…0.35mg Sugar Free Syrup	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1234.	075462	Letose Syrup Each 5ml Contains: Iron III Hydroxide Polymaltose Complex…50mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1235.	075463	Medfir 10mg Tablet Each Tablet Contains: Adefovir Dipivoxil…10mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1236.	075464	Medcavir 0.5mg Tablet Each Tablet Contains: Entecavir as Monohydrate…0.5mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1237.	075465	T-Poxi 20mg Tablet Each Film Coated Tablet Contains: Paroxitine (as HCl)…20mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1238.	075466	Ice 30 Capsule Each Capsule Contains: Lansoprazole (Pellets)…30mg Source : M/s Vision Pharmaceuticals Islamabad.	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1239.	075467	Olx 20mg Capsule Each Capsule Contains: Omeprazole (Pellets)…20mg Source : M/s Vision Pharmaceuticals Islamabad.	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1240.	075468	D-Lox 40mg Capsule Each Capsule Contains: Duloxetine as HCl (Pellets)…40mg Source : M/s Vision Pharmaceuticals Islamabad.	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		-do-
1241.	075469	Kanamed 1gm Injection Each 4ml Ampoule Contains: Kanamycin Sulphate eq. to Kanamycin Base…1000mg	25-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		Latest GMP report is not submitted. Valid DML is not submitted.
1242.	075472	Medka 100mg Injection Each Vial Contains: Amikacin (as Sulphate)…100mg	31-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		Latest GMP report is not submitted. Valid DML is not submitted.

1243.	075473	Medka 250mg Injection Each Vial Contains: Amikacin (as Sulphate)…250mg	31-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		Latest GMP report is not submitted. Valid DML is not submitted.
1244.	075474	Medka 500mg Injection Each Vial Contains: Amikacin (as Sulphate)…500mg	31-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-		Latest GMP report is not submitted. Valid DML is not submitted.
M/s. Venus Pharma, 23-Km Multan Road, Lahore						
1245.	13993	Xylex 2% Injection with Adrenaline Contains: Lignocaine HCl…2%w/v Adrenaline…0.001%w/v	28-07-1993	Dy. No. 24679 dated 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 19-03-2019 which has not yet been responded by the firm.

Decision: Registration deferred the above cases for rectification of shortcomings as mentioned against each and advised to issue a final reminder.

ii. Veterinary (Local)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Remarks (if any)
M/s. Attabak Pharmaceuticals, Plot No. 5C, Industrial Area I-10/3, Islamabad						
1246.	48159	Levofas Gold Oral Suspension Each 100ml Contains: Levamisole HCl…3gm Oxyclozanide…6gm Cobalt Chloride…0.764gm Sodium Selenite…0.076	12-07-2008	Dy. No. 23438 dated 06-07-2018 10000/-		The production of firm was resumed for Oral Powder (vet) and Oral Liquid section (vet), however production activity in the liquid injectable section (vet) shall remain suspended vide DRAP letter No. F.4-8/ 2001-QA dated 22-2-2019
1247.	48160	Respitil Aqueous Concentrate Each ml Contains: Tilmicosin (as Phosphate)…250mg	12-07-2008	Dy. No. 23439 dated 06-07-2018 10000/-		-do-
1248.	48161	Levacid Oral Solution Each 100ml Contains: Levamisole HCl…1.5gm	12-07-2008	Dy. No. 23440 dated 06-07-2018 10000/-		-do-
1249.	48162	Pulmorol-T Aqueous Solution Each ml Contains: Tylosin Tartrate…100mg Doxycycline HCl…200mg Bromohexine HCl…10mg	12-07-2008	Dy. No. 23441 dated 06-07-2018 10000/-		-do-

1250.	48163	Meloxibak Injection Each ml Contains: Meloxicam…7.5mg	12-07-2008	Dy. No. 23442 dated 06-07-2018 10000/-		-do-
1251.	48164	Albak Granules Each kg Contains: Albendazole…200gm	12-07-2008	Dy. No. 23443 dated 06-07-2018 10000/-		-do-
1252.	48165	AXY-Vit Powder Each 450g Powder Contains: oxytetracycline HCl…50g Vitamin A…2,000,000IU Vitamin D3…360,000IU Vitamin E…800mg Vitamin K…720mg Vitamin B2…300mg Vitamin B12…200mcg Niacinamide…12000mg Calcium-D-Pentothenate…4600mg	12-07-2008	Dy. No. 23444 dated 06-07-2018 10000/-		-do-
1253.	48166	Fosfabak Injection Each ml Contains: Toldimfos Sodium…100mg (Source of Phosphours in Medicine)	12-07-2008	Dy. No. 23445 dated 06-07-2018 10000/-		-do-
1254.	48167	Gentabak-Plus Injection Each ml Contains: Gentamycin (as Sulphate)…30mg Trimethoprim…25mg Sulphadimidine…125mg	12-07-2008	Dy. No. 23446 dated 06-07-2018 10000/-		-do-
1255.	48168	Toltrabak Oral Solution Each ml Contains: Toltrazuril…25mg	12-07-2008	Dy. No. 23447 dated 06-07-2018 10000/-		-do-
1256.	48169	Gentylobak Injection Each ml Contains: Gentamycin (as Sulphate)…50mg Tylosin (as Tartrate)…100mg	12-07-2008	Dy. No. 23448 dated 06-07-2018 10000/-		-do-
1257.	48170	Tiamubak 45% Oral Powder Each 100gm Contains: Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…45gm	24-07-2008	Dy. No. 23452 dated 06-07-2018 10000/-		-do-
1258.	48173	Levofas Oral Suspension Each 100ml Contains: Levamisole HCl…1.5gm Oxyclozanide…3gm Cobalt Chloride…0.382gm	24-07-2008	Dy. No. 23454 dated 06-07-2018 10000/-		-do-
1259.	48174	Asper-Cool Water Soluble Powder Each 1000gm Contains: Acetylsalicyclic Acid…67gm Vitamin C…200gm Potassium Chloride…3gm Sodium Citrate…7gm	24-07-2008	Dy. No. 23455 dated 06-07-2018 10000/-		-do-

1260.	48171	Colibak Injection Each 100ml Contains: Colistin Sulphate…20MIU	24-07-2008	Dy. No. 23453 dated 06-07-2018 10000/-		-do-
1261.	48176	Tylometrol Injection Each ml Contains: Tylosin Tartrate…50mg Colistin Sulphate…10mg Dimetridazole…100mg	12-07-2008	Dy. No. 23449 dated 06-07-2018 10000/-		-do-
1262.	48177	EC-Cool Plus Oral Suspension Each 1000ml Contains: Ascorbic Acid…200gm Potassium Chloride…3gm Sodium Chloride…19gm Sodium Citrate…7.8gm	12-07-2008	Dy. No. 23450 dated 06-07-2018 10000/-		-do-
1263.	48178	Oxfenda Gold Oral Suspension Each ml Contains: Oxfendazole…22.65mg Cobalt Chloride…3.82mg Sodium Selenite…0.35mg	12-07-2008	Dy. No. 23451 dated 06-07-2018 10000/-		-do-
M/s. SB Pharma, Plot No. 5-F, Industrial Triangle, Kahuta Road, Islamabad						
1264.	48219	SB Tiamulin Oral Powder Each 100gm Contains: Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…12.5gm	18-07-2008	Dy. No. 24513 dated 16-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-04-2019 which has not yet been responded by firm
1265.	48221	SB Tiamulin 45% Oral Powder Each 100gm Contains: Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…45gm	18-07-2008	Dy. No. 24513 dated 16-07-2018 10000/-		-do-
1266.	48222	SB Protectine Oral Powder Each 1000gm Contains: Tylosine Tartrate eq. to Tylosine Base…100gm Doxycycline HCl eq. to Doxycycline Base…200gm Colistine Sulphate eq. to Colistine Base…500MIU Phenylbutazone…12gm Bromohexine…5gm	18-07-2008	Dy. No. 24513 dated 16-07-2018 10000/-		-do-
1267.	48223	SB Tiaclor Oral Powder Each 1000gm Contains: Tiamulin Hydrogen Fumarate eq. to Tiamulin Base…100gm Chlortetracycline HCl eq. to Chlortetracycline Base…300gm	18-07-2008	Dy. No. 24513 dated 16-07-2018 10000/-		-do-
1268.	48224	SB Exitil Oral Suspension Each 100ml Contains:	18-07-2008	Dy. No. 24513 dated		-do-

		Albendazole…12.5%		16-07-2018 10000/-		
M/s. Star Laboratories (Pvt) Ltd., 23-Km Multan Road (Chung), Lahore						
1269.	49550	Alvenax-150 bolus Each bolus contains: Albendazole 150mg	29-07-2008	Dy. No. 24511 dated 16-07-2018 10000/-		i. GMP report submitted id of year 2015 ii. Section approval is also not provided by the firm.
1270.	49551	Alvenax-300 bolus Each bolus contains: Albendazole 300mg	29-07-2008	Dy. No. 24511 dated 16-07-2018 10000/-g6		-do-
1271.	49552	Alvenax-360 bolus Each bolus contains: Albendazole 360mg	29-07-2008	Dy. No. 24511 dated 16-07-2018 10000/-		-do-
1272.	49554	Tetraclozan Sheep 900 bolus Each bolus contains: Tetramisole HCL 450mg Oxyclozanide 450mg	29-07-2008	Dy. No. 24511 dated 16-07-2018 10000/-		-do-
1273.	49553	Nizam Bolus Each bolus contains: Levamisole 1000mg Oxyclozanide 1400mg	29-07-2008	Dy. No. 24511 dated 16-07-2018 10000/-		-do-
1274.	30808	Glucoride-1 Tablets Each tablet contains: Glimepride…….1mg	04-08-2003	Dy. No. 25885 dated 27-07-2018 10000/-		-do-
1275.	30809	Glucoride -2 Tablets Each tablet contains: Glimepride…….2mg	04-08-2003	Dy. No. 25885 dated 27-07-2018 10000/-		-do-
1276.	30810	Tyzitec Syrup Each 5ml contains: Cetirizine Dihydrochloride…..5mg	04-08-2003	Dy. No. 25885 dated 27-07-2018 10000/-		-do-
1277.	4347	Water for injection	18-07-1978	Dy. No. 24510 dated 16-07-2018 10000/-		-do-
1278.	30802	Stardone Tablets Each tablet contains: Domperidone 10mg	25-07-2003	Dy. No. 24510 dated 16-07-2018 10000/-		-do-
1279.	30803	Stardone Suspension Each 1ml contains: Domperidone 1mg	25-07-2003	Dy. No. 24510 dated 16-07-2018 10000/-		-do-
1280.	30804	Stargesic tablet Each tablet contains: Orphenadrine Citrate 35mg Paracetamol 450mg	25-07-2003	Dy. No. 24510 dated 16-07-2018 10000/-		-do-
1281.	14141	PENICILLIN-40 INJECTION Each Vial Contains:	01-08-1993	Dy. No. 25886 dated 27-07-2018		-do-

		BENZYL PENICILLIN 1000000 I.U. PROCAINE PENICILLIN 3000000 I.U.		10000/-		
1282.	14142	OXAZOL DRENCH Each ml contains: OXFANDAZOLE 2.265%	01-08-1993	Dy. No. 25886 dated 27-07-2018 10000/-		-do-
1283.	14143	OXYCORT SPRAY Each 300ML contains: OXYTETRACYCLINE HCL 1500MG Hydrocortisone…480mg	01-08-1993	Dy. No. 25886 dated 27-07-2018 10000/-		-do-
M/s. Symans Pharmaceuticals (Pvt) Ltd., 10-Km Sheikhupura Road, Lahore						
1284.	14133	Symostress Water Soluble and Feed Additive Powder EACH KG CONTAINS: Vitamin A…15,000,000IU Vitamin D3…3,000,000IU Vitamin E…6000mg Vitamin K3…4000mg Vitamin B1…5000mg Vitamin B2…6000mg Vitamin B6…4000mg Vitamin B12…9000mcg Vitamin C…15000mg Folic Acid…750mg Nicotinic Acid…25000mg Calcium Pantothenate…10,000mg	01-08-1993	Dy. No. 24597 dated 16-07-2018 10000/-		Valid DML is not attached. Latest GMP report provided is of 2016.
M/s. Breeze Pharma (Pvt) Ltd., (125-126-127) A, Industrial Triangle, Kahuta Road, Islamabad						
1285.	75666	ALBA 10 SUSPENSION Each 100 ml contains: ALBENDAZOLE ……10% W/V SODIUM SELENITE……...0.035% W/V COBALT CHLORIDE……..0.075% W/V	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 22-3-2019 which has not yet been responded by the firm.
1286.	75662	ALMOXIN-C WATER SOLUBLE POWDER Each gm Contains: AMOXYCILLIN TRIHYDRATE ……..200MG COLISTIN SULPHATE.... 60,00,000 IU	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1287.	75677	AVICOX WATER SOLUBLE POWDER EACH KG CONTAINS: SULPHAQUINOXALINE (SODIUM)…….200,000 MG, SULPHADIMIDINE (SODIUM)……...82,500MG , DIAVERIDINE…..40, 000MG, VITAMIN A….28, 00,000IU, VITAMIN K3……...2000MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-

1288.	75668	COXIKIL WATER SOLUBLE POWDER Each 1000gm contains: 2,4-DIAMINO-5 (VERATRYPYRIMIDINE).. 25GM SULPHABENZYLPYRAZINE……100GM VIT-A…….12,50,000 IU VIT-K3……..2.5GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1289.	75654	DIMOX INJECTION Each ml contains: SULPHADIMIDINE (AS SODIUM)……33% W/V	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		
1290.	75663	ENROCAM LIQUID Each 100 ml contains: ENROFLOXACIN…….10 GM COLISTIN SULPHATE……. 3GM AMANTADINE……..... 4GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1291.	75673	Rodox Water Soluble Powder Each 100gm Contains: TYLOSIN TARTRATE……10GM DOXYCYCLINE HCI…..20GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1292.	75652	MELONAC PLUS INJECTION Each ml contains: MELOXICAM…… ...10MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1293.	75671	MOTIL LIQUID Each ml contains: TILMICOSIN PHOSPHATE……250MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1294.	75659	NCO-60 WATER SOLUBLE POWDER Each gm Contains: OXYTETRACYCLINE HCI……...20% W/V COLISTIN SULPHATE…….20% W/V NEOMYCIN…..20% W/V	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1295.	75661	OXYTRON 100 INJECTIONS Each ml contains: OXYTERTRACYCLNE...100MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1296.	75653	OXYTRON LA INJECTION Each ml contains: OXYTERTRACYCLINE ….200MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1297.	75676	PYRAMINOL INJECTION Each ml contains: DIMINAZINE ACETURATE…….105MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-

		ANTIPYRINE……...131MG				
1298.	75660	RAPID-TD WATER SOLUBLE POWDER EACH 100 GM CONTAINS: TYLOSIN TARTARATE ….20 GMDOXYCYCLINE HYCLATE ……....25 GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1299.	75656	RESPORAL LIQUID Each ml contains: TYLOSIN TARTRATE…...100MG DOXYCYCLINE HCI ...200MG COLISTIN SULPHATE…….500000 IU BROMHEXINE HCL ….....2MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1300.	75674	SOLODEX INJECTION. Each ml contains: PREDNISOLONE (AS ACETATE)……7.5MG DEXMETHASONE (AS SODIUM PHOSPHATE)…….....2.5MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1301.	75667	SOLVITA-S SOLUTION Each 100 ml contains: VITAMIN E…...5.00GM SODIUM SELENITE ...15.00MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1302.	75672	SUPER FLUSH WATER SOLUBLE POWDER EACH KG CONTAINS: FUROSEMIDE……...20G M, POTASSIUM CHLORIDE….4GM, CALCIUM CARBONATE...45GM, MANGANESE SULPHATE...1GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1303.	75658	SUPER LEVA WATER SOLUBLE POWDER Each 100gm Contains: LEVAMISOLE HCL …….15%	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1304.	75669	TOLZUR PLUS LIQUID Each 100 ml contains: TOLTRAZURIL……2.5GM VIT-K3……..0.2GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1305.	75657	TRICLOFON POWDER Each gm Contains: TRICHLORFON…. 985MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1306.	75670	TY-DOX PLUS LIQUID EACH 1000ML CONTAINS: TYLOSINTARTRATE…...1 00GM, DOXYCYCLINE HCI…200GM, COLISTIN SULPHATE.500 MIU,	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-

		BROMHEXINE…..12GM				
1307.	75655	TYLOX-20 INJECTION Each ml contains: TYLOSIN (AS TARTARATE)……..200MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1308.	75664	Y-Gent 5% Injection Each ml contains: GENTAMYCIN SULPHATE EQUAL TO 50MG GENTAMYCIN BASE	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
M/s. Mallard Pharmaceuticals (Pvt) Ltd., 23-Km Lahore Road, Multan.						
1309.	049561	Target 10 Liquid Each ml Contains: Fenbendazole…10mg	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		GMP report dated 14-11-2018 concludes that "The production in inject able section should be stopped till the improvements are made. The management was also advised to improve and remove the shortcomings pointed out in other areas of the premises during the course of inspection and compliance report should be submitted. The re-inspection will be conducted accordingly for be verification.
1310.	049562	Wealdox Powder Each kg Contains: Doxycycline HCl…200gm	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
1311.	049563	Wealcol Powder Each 100gm Contains: Colistin Sulphate…500,000.000IU	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
1312.	049564	Wealcoc Powder Each kg Contains: Amprolium…200gm Furaltadone…200gm Vitamin K3…5gm	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
1313.	049565	Neoct-C Powder Each kg Contains: Colistin Sulphate…8gm Neomycin…140gm Chlortetracycline…160gm	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
1314.	049566	Liso 10 Powder Each gm Contains: Lysozyme…22% Vitamin E 50 SD…0.5%	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-

1315.	049567	Daro Mall Powder Each 100gm Contains: Neomycin Sulphate…400mg Streptomycin Sulphate…400mg Suphaguanidine…4gm Kaolin…4gm Pectin…400mg Bismuth Subnitrate…2gm Vitamin A…8000IU	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
1316.	049568	Enromall 20 Liquid Each ml Contains: Enrofloxacin…200mg	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
1317.	049569	Saprox Liquid Each ml Contains: Sulphadiazine…35.500mg Sulphadimidine…28.400mg Neomycin Sulphate…1.800gm Hyoscine Methyl bromide…0.040mg Pectin…7.100gm Kaolin…103.3mg Vitamin B1…0.150mg Vitamin B2…0.220mg	07-08-2008	Dy. No. 24771 dated 17-07-2018 10000/-		-do-
M/s. Efroze Chemical Industries (Pvt) Ltd., 146/23, Korangi Industrial Area, Karachi						
1318.	048811	Declot Tablet Each tablet contains:: Clopidogrel (as Bisulphate)….75mg(USP Specification)	22-07-2008	Dy. No. 23433 dated 06-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 25-04-2019 which has not yet been responded by the firm.
1319.	048815	Efome Capsule Each Capsule Contains:: Omeprazole enteric coated pellets eq. to Omeprazole……40mg	22-07-2008	Dy. No. 23433 dated 06-07-2018 10000/-		-do-
1320.	048816	Efrozole 20mg Capsule Each capsules contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate) …20mg	22-07-2008 06-05-2010	Dy. No. 23433 dated 06-07-2018 10000/-		-do-
1321.	048817	Efrozole 40mg Capsule Each capsules contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate)….40mg	22-07-2008 06-05-2010	Dy. No. 23433 dated 06-07-2018 10000/-		-do-
1322.	048812	Montef 4mg Chewable Tablet Each chewable tablet contains: Montelukast (as Sodium) …….4mg	22-07-2008	Dy. No. 23433 dated 06-07-2018 10000/-		-do-

1323.	048813	Montef 5mg Chewable Tablet Each chewable tablet contains: Montelukast (as Sodium)…….5mg	22-07-2008	Dy. No. 23433 dated 06-07-2018 10000/-		-do-
1324.	048814	Montef 10mg Tablet Each film coated tablet contains:: Montelukast (as Sodium)…10mg	22-07-2008	Dy. No. 23433 dated 06-07-2018 10000/-		-do-
M/s. Breeze Pharma (Pvt) Ltd., (125-126-127) A, Industrial Triangle, Kahuta Road, Islamabad						
1325.	75666	ALBA 10 SUSPENSION Each 100 ml contains: ALBENDAZOLE ……10% W/V SODIUM SELENITE……...0.035% W/V COBALT CHLORIDE…..0.075% W/V	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 22-3-2019 which has not yet been responded by the firm.
1326.	75662	ALMOXIN-C WATER SOLUBLE POWDER Each gm Contains: AMOXYCILLIN TRIHYDRATE …..200MG COLISTIN SULPHATE…..... 60,00,000 IU	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1327.	75677	AVICOX WATER SOLUBLE POWDER EACH KG CONTAINS: SULPHAQUINOXALINE (SODIUM)…….200,000 MG, SULPHADIMIDINE (SODIUM)…….....82,500MG , DIAVERIDINE…...40, 000MG, VITAMIN A….28, 00,000IU, VITAMIN K3……...2000MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1328.	75668	COXIKIL WATER SOLUBLE POWDER Each 1000gm contains: 2,4-DIAMINO-5 (VERATRYPYRIMIDINE).. 25GM SULPHABENZYLPYRAZI NE……100GM VIT-A…….12,50,000 IU VIT-K3……..2.5GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1329.	75654	DIMOX INJECTION Each ml contains: SULPHADIMIDINE (AS SODIUM)……33% W/V	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1330.	75663	ENROCAM LIQUID Each 100 ml contains: ENROFLOXACIN….10GM COLISTIN SULPHATE……. 3GM AMANTADINE.. 4GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-

1331.	75673	Rodox Water Soluble Powder Each 100gm Contains: TYLOSIN TARTRATE……10GM DOXYCYCLINE HCI…..20GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1332.	75652	MELONAC PLUS INJECTION Each ml contains: MELOXICAM… ...10MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1333.	75671	MOTIL LIQUID Each ml contains: TILMICOSIN PHOSPHATE……250MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1334.	75659	NCO-60 WATER SOLUBLE POWDER Each gm Contains: OXYTETRACYCLINE HCI……...20% W/V COLISTIN SULPHATE…….20% W/V NEOMYCIN…..20% W/V	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1335.	75661	OXYTRON 100 INJECTIONS Each ml contains: OXYTERTRACYCLNE….. 100MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1336.	75653	OXYTRON LA INJECTION Each ml contains: OXYTERTRACYCLINE ….200MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1337.	75676	PYRAMINOL INJECTION Each ml contains: DIMINAZINE ACETURATE…….105MG ANTIPYRINE……...131MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1338.	75660	RAPID-TD WATER SOLUBLE POWDER EACH 100 GM CONTAINS: TYLOSIN TARTARATE ….20 GMDOXYCYCLINE HYCLATE ……....25 GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1339.	75656	RESPORAL LIQUID Each ml contains: TYLOSIN TARTRATE…...100MG DOXYCYCLINE HCI ...200MG COLISTIN SULPHATE…….500000 IU BROMHEXINE HCL ……..2MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1340.	75674	SOLODEX INJECTION. Each ml contains: PREDNISOLONE (AS ACETATE)……7.5MG DEXMETHASONE (AS SODIUM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-

		PHOSPHATE)…….....2.5MG				
1341.	75667	SOLVITA-S SOLUTION Each 100 ml contains: VITAMIN E…...5.00GM SODIUM SELENITE …….....15.00MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1342.	75672	SUPER FLUSH WATER SOLUBLE POWDER EACH KG CONTAINS: FUROSEMIDE……...20GM, POTASSIUM CHLORIDE….4GM, CALCIUM CARBONATE...45GM, MANGANESE SULPHATE...1GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1343.	75658	SUPER LEVA WATER SOLUBLE POWDER Each 100gm Contains: LEVAMISOLE HCL …….15%	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1344.	75669	TOLZUR PLUS LIQUID Each 100 ml contains: TOLTRAZURIL……2.5GM VIT-K3……..0.2GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1345.	75657	TRICLOFON POWDER Each gm Contains: TRICHLORFON……. 985MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1346.	75670	TY-DOX PLUS LIQUID EACH 1000ML CONTAINS: TYLOSINTARTRATE ..100GM, DOXYCYCLINE HCI…200GM, COLISTIN SULPHATE.500 MIU, BROMHEXINE……...12GM	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1347.	75655	TYLOX-20 INJECTION Each ml contains: TYLOSIN (AS TARTARATE)……..200MG	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
1348.	75664	Y-Gent 5% Injection Each ml contains: GENTAMYCIN SULPHATE EQUAL TO 50MG GENTAMYCIN BASE	04-06-2013	Dy. No. 25778 dated 24-07-2018 20000/-		-do-
M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, A-127, S.I.T.E., Super Highway, Karachi						
1349.	48183	Oxytetracycline 10% Injectable Solution Each ml Contains: Oxytetracycline HCl…100mg	17-07-2008	Dy. No. 23435 dated 06-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 and 09-04-2019 which has not yet been responded by the firm.

1350.	48184	Tylosin 20% Injectable Solution Each ml Contains: Tylosine (as Tartrate)…200mg	17-07-2008	Dy. No. 23435 dated 06-07-2018 10000/-		-do-
1351.	49536	Alfamycine 10% Injectable Solution Each ml Contains: Gentamicin (as Sulphate)…100mg	22-07-2008	Dy. No. 22814 dated 02-07-2018 10000/-		-do-
1352.	48180	Alfamec 1% Injectable Solution Each ml Contains: Ivermectin…10mg	12-07-2008	Dy. No. 22816 dated 02-07-2018 10000/-		-do-
1353.	48181	Xylazine 2% Injectable Solution Each ml Contains: Xylazine (as HCl)…20mg	12-07-2008	Dy. No. 22816 dated 02-07-2018 10000/-		-do-
1354.	48182	Lincomycine-Spectinomycin 5/10 Injectable Solution Each ml Contains: Lincomycin (as HCl)…50mg Spectinomycin (as HCl)…100mg	12-07-2008	Dy. No. 22816 dated 02-07-2018 10000/-		-do-
1355.	48185	Multivitamin Injectable Solution Each ml Contains: Vitamin A (as Synthetic Concentrate Oily Form)…15,000IU Cholecalciferol (as Concentrate Oily Form)…1000IU Alpha tocopheryl Acetate…20mg Thiamine HCl…10mg Riboflavine Sodium Phosphate…6.85mg Pyridoxin HCl…3mg Cyanocobalamin…50mcg Nicotinamide…35mg Dexpanthenol...25mg	12-07-2008	Dy. No. 22815 dated 02-07-2018 10000/-		-do-
1356.	48269	Altrim Injectable solution Each ml contains: Sulphadiazine Sodium 200mg Trimethoprin 40mg	17-07-2008	Dy. No. 24677 dated 16-07-2018 10000/-		-do-
1357.	48270	Oxyla 10% Injectable Contains: Oxytetracycline HCL 100mg	17-07-2008	Dy. No. 24677 dated 16-07-2018 10000/-		-do-
1358.	48271	Colistin S Injectable solution Each ml contains: Colistin Sulphate 200000IU	17-07-2008	Dy. No. 24677 dated 16-07-2018 10000/-		-do-
1359.	48272	Almec 1% Injectable solution Each ml contains:	17-07-2008	Dy. No. 24677 dated		-do-

		Ivermection 10mg		16-07-2018 10000/-		
1360.	48273	Oxyta Injectable solution Each ml contains: oxytetracycline 200mg	17-07-2008	Dy. No. 24677 dated 16-07-2018 10000/-		-do-
1361.	48282	Altrim pus Injectable solution Each ml contains: Sulphadiazine Sodium 400mg Trimethoprin 80mg	17-07-2008	Dy. No. 24676 dated 16-07-2018 10000/-		-do-
1362.	48283	Alfacin 5% Injectable solution Each ml contains: Gentamicin 50mg	17-07-2008	Dy. No. 24676 dated 16-07-2018 10000/-		-do-
1363.	48284	Alfacin 10% injectable solution Each ml contains: Gentamicin 100mg	17-07-2008	Dy. No. 24676 dated 16-07-2018 10000/-		-do-
1364.	48285	Floxin 10% injectable solution Each ml contains: Norfloxacin 100mg	17-07-2008	Dy. No. 24676 dated 16-07-2018 10000/-		-do-
1365.	48290	Genta-AC Injection Each ml Contains: Gentamycin…25mg Amoxicillin…50mg	17-07-2008	Dy. No. 24675 dated 16-07-2018 10000/-		-do-
1366.	48291	Colitylo DM Injection Each ml Contains: Colistin Sulphate…10mg Tylosin Tartrate…50mg Dimetridazole…100mg	17-07-2008	Dy. No. 24675 dated 16-07-2018 10000/-		-do-
1367.	48292	Spec-Lin Injection Each ml Contains: Lincomycin…50mg Spectinomycin…100mg	17-07-2008	Dy. No. 24675 dated 16-07-2018 10000/-		-do-
1368.	48278	Alfacin 15% Injectable Solution Each ml Contains: Gentamycin…150mg	17-07-2008	Dy. No. 24674 dated 16-07-2018 10000/-		-do-
1369.	48279	C-Phenicol Injectable Solution Each ml Contains: Chloramphemicol…200mg	17-07-2008	Dy. No. 24674 dated 16-07-2018 10000/-		-do-
1370.	48280	Vutazon SS Injectable Solution Each ml Contains: Phenylbutazone…200mg	17-07-2008	Dy. No. 24674 dated 16-07-2018 10000/-		-do-
1371.	48281	Tylosin 20% Injectable Solution Each ml Contains: Tylosin…200mg	17-07-2008	Dy. No. 24674 dated 16-07-2018 10000/-		-do-
1372.	48266	Ciprolina 20% Solution Each 100ml Contains: Ciprofloxacin…20gm	22-07-2008	Dy. No. 25290 dated 20-07-2018 10000/-		-do-

1373.	48267	Flumicon-50 Powder Each kg Contains: Flumequine…500gm	22-07-2008	Dy. No. 25290 dated 20-07-2018 10000/-		-do-
1374.	48268	T-Mycin Oral Solution Each ml Contains: Tilmicosin…250mg	22-07-2008	Dy. No. 25290 dated 20-07-2018 10000/-		-do-
1375.	48286	Dinsolone Injection Each ml Contains: Prednisolone…25mg	22-07-2008	Dy. No. 25288 dated 20-07-2018 10000/-		-do-
1376.	48287	Enflox 5% Injectable Solution Each ml Contains: Enrofloxcacin…50mg	22-07-2008	Dy. No. 25288 dated 20-07-2018 10000/-		-do-
1377.	48288	Foxylina Injection Each ml Contains: Oxytetracycline…300mg (as eq. to Oxytetracycline Dihydrate) Flunixin Meglumine…20mg	22-07-2008	Dy. No. 25288 dated 20-07-2018 10000/-		-do-
1378.	48289	Methasolone Injection Each ml Contains: Prednisolone…7.5mg Dexamethasone…2.5mg	22-07-2008	Dy. No. 25288 dated 20-07-2018 10000/-		-do-
1379.	48293	Doctyl Plus E/S Powder Each 100gm Contains: Tylosin Tartrate…20gm Doxycycline HCl…40gm	17-07-2008	Dy. No. 24074 dated 11-07-2018 10000/-		-do-
1380.	48294	Tycoli Powder Each 100gm Contains: Tylosin Tartrate (Vet)…10gm Doxycycline HCl (Vet)…20gm Colistin Sulphate (Vet)…500MIU Bromohexine (Vet)…5gm Phenyl Butazone (Vet)…12gm	17-07-2008	Dy. No. 24074 dated 11-07-2018 10000/-		-do-

Decision: Registration deferred the above cases for rectification of shortcomings as mentioned against each and advised to issue a final reminder.

Finished Import Human (Reference)

Sr. No	Reg. No.	Name of Manufacturer	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Remarks (if any)
1381.	021129	M/s. Novartis Pharma (Pakistan) Ltd, 15 West Wharf, Dockyard Road, Karachi	Femara 2.5mg Tablet Each Tablet Contains: Letrozole…2.5 mg	01-08-1998	Dy. No. 23437 dated 06-07-2018 20000/-		Letter dated 5-3-2019 communicated for shortcomings but firm didn't responded yet.
1382.	047676	M/s. Atco Pharma International (Pvt) Ltd., B-18, S.I.T.E., Karachi	FEMIZET TABLETS 1MG Each FILM COATED TABLETS contains: ANASTROZOLE IH*…1MG (In House)	05-08-2008	Dy. No. 25638 dated 24-07-2018 20000/-	Imported Change: 04-01-2010	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.

Decision: Registration deferred the above cases for rectification of shortcomings as mentioned against each and advised to issue a final reminder.

Finished Import Human (Non-reference)

Sr. No	Reg. No.	Name of Manufacturer	Brand Name, Composition & Specification	Date of Initial Registration	Date of application (R&I) Fee submitted	Remarks (if any)
M/s. Medi Mark Pharmaceuticals, 588-B/1, LiaquatChowk, Sahiwal						
1383.	21920	M/s Korea Pharma Co. Ltd., Korea.	Traxef 250mg IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…250mg	05-09-1998	Dy. No. 25152 dated 19-07-2018 20000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019 which has not yet been responded by the firm.
1384.	21919	M/s Korea Pharma Co. Ltd., Korea.	Traxef 500mg IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…500mg	05-09-1998	Dy. No. 25151 dated 19-07-2018 20000/-	
1385.	21921	M/s Korea Pharma Co. Ltd., Korea.	Traxef 1gm IM Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…1gm	05-09-1998	Dy. No. 25150 dated 19-07-2018 20000/-	
1386.	21200	M/s Korea Pharma Co. Ltd., Korea.	Traxef 1gm IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…1gm	05-09-1998	Dy. No. 25149 dated 19-07-2018 20000/-	

1387.	21923	M/s Korea Pharma Co. Ltd., Korea.	Traxef 250mg IM Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…250mg	05-09-1998	Dy. No. 25148 dated 19-07-2018 20000/-	
1388.	21922	M/s Korea Pharma Co. Ltd., Korea.	Traxef 500mg IM Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…500mg	05-09-1998	Dy. No. 25147 dated 19-07-2018 20000/-	

Decision: Registration deferred the above cases for rectification of shortcomings as mentioned against each and advised to issue a final reminder.

Finished Import Veterinary (Reference)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Remarks (if any)
M/s. Better Traders International, 23-Z, Saifullah Shaheed Road, Madina Town, Faisalabad						
1389.	049560	Kepromec Oral Each ml Contains: Ivermectin…10mg	24-07-2008	Dy. No. 24773 dated 17-07-2018 10000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 19-3-2019 which has not yet been responded by the firm.
M/s. Vet Line International, Flat No. 55/5, First Floor, Shadman Market, Lahore						
1390.	049749	Tylo-Suscit Powder Each gm Contains: Tylosin Tartrate…250mg	25-09-2008	Dy. No. 23134 dated 04-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 09-4-2019 which has not yet been responded by the firm.
1391.	049750	Sulfaclozin Na 60% Powder Each gm Contains: Sulfaclozin Sodium…600mg	25-09-2008	Dy. No. 23134 dated 04-07-2018 20000/-		
M/s. ICI Pakistan Ltd., 5-West Wharf, Karachi						
1392.	003023	Nilzan Bolus Each Bolus Contains: Tetramisole HCl B.Vet.C…2gm Oxyclozanide BP Vet…1.4gm	26-07-1993	Dy. No. 25034 dated 18-07-2018 20000/-		Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 19-3-2019 which has not yet been responded by the firm.
1393.	003021	Nilverm Bolus Each Bolus Contains:	26-07-1993	Dy. No. 25033 dated 18-		

		Tetramisole HCl B.Vet.C…2gm		07-2018 20000/-		

Decision: Registration deferred the above cases for rectification of shortcomings as mentioned against each and advised to issue a final reminder.

Miscellaneous Cases

i. Cases deferred in 286th meeting of Registration Board.

a. 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 of products are as under:

Reg. No	Brand Name & Composition	Date of registration as per Form-5B
012777	Pain Gay Ointment Each gm contains: Methyl salicylate ……150mg 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 that aforementioned 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.

The above case was discussed in the 288th meeting of Registration Board wherein the board decided as under:

"Registration Board deferred the case for the submission of copy of FIR related to documents stolen/misplaced/lost for onward consideration of case"

The firm has now submitted the copy of daily dairy record of concerned Police Station regarding the report of stolen/ misplaced/ lost registration letter. Submitted for consideration please.

Decision: Registration Board deferred the above case for opinion of Legal Affairs Division.

b. M/s Trigon Pharmaceuticals Pvt Limited Lahore.

Sr. No.	Reg. No.	Product Name	Initial date of Registration	Application Receiving date
1.	047757	Pantagon Injection IM/IV Each 1ml contains:- Pentazocine (as Lactate) … 30mg	25-10-2007	**Due date (24-10-2017)** Fee of Rs.10,000/- deposited on 25-10-2017. As application received within 60 days after expiry of Reg. Remaining Fee of Rs.10,000/- deposited on 23-04-2018.
2.	047758	Bubrifen Injection Each ml contains:- Buprenorphen (as HCl) … 0.3mg	Do	Do

The above products were considered in the 286th meeting of Registration Board wherein the Board decided as under:

"Registration Board deferred the case for the confirmation of status of License from Licensing Division"

It is submitted that CLB in its 267th meeting after decision of PQCB decided that no further action is warranted. The decision of PQCB is as under:

The Board after considering the inspection report , due deliberation and discussion decoded to allow M/s Trigon Pharmaceuticals Pvt Limited Lahore to resume production operations in Cephalosporin dry Powder injection, Psychotropic Injectable , Steroidal Injections and General liquid Injections (vials, ampoules), strictly in accordance with law.

Decision: Registration Board acceded to the request of firm and decided to grant renewal w.e.f. 25-10-2017 to 24-10-2022.

ii. Cases referred by other Sections/ Divisions.

a. **Transfer of Registration from M/s The Searle Company Limited Karachi to M/s ICI Pakistan Limited Karachi**.

Reg-I section has informed that M/s ICI Pakistan Limited Karachi has requested for change of registration status of following products from M/s The Searle Company Limited Karachi to their name. Details are as under:

Sr. No.	Reg. No.	Brand name & composition
1.	001318	Ketress tablet 40mg Each tablet contains: Levamisole HCL BP 47.2mg Eq. to 40mg as Levamisole
2.	001317	Ketress Syrup Each 5ml contains: Levamisole 40mg(as HCl 47.2mg)

After securitization of the documents, following are the observations:

i. The product was registered in the name of M/s Serale Pakistan Pvt Limited Karachi on 12-12-1991vide letter No. F.3-9/91-Reg-II (M-97). However the change brand name was granted in name of M/s ICI Pakistan Limited Karachi on 23-11-2002 vide letter No. F-6-11/ 2002 –Reg-II.
ii. The renewal from 2007-2012 was again granted in name of M/s Searle Pakistan Limited Karachi on dated 16-11-2007. Moreover the renewal for the year 2012 and 2017 was also submitted by M/s Searle Pakistan Karachi.
iii. The title of the firm was changed from M/s Serale Pakistan Pvt Limited Karachi to The Searle Company Limited Karachi by the Licensing Division on 29-8-2013, however the transfer letter in new name has not been submitted by the firm.

Decision: Registration Board deferred the above case for opinion of Legal Affairs Division.

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iv. Cases For Differential Fee

a) M/s. Atco Laboratories Limited, Karachi

Sr. No	Reg. No	Products/Name	Initial Date of Registration	Application receiving date and fee submitted date and due date
1	044868	Fytosid 100mg Injection Each ml contains Etoposide USP…20mg **Manufactured by M/s Dabur Pharma Ltd,India**	15-02-2007 Change of manufacturer name 04-01-2010 Fresenius Kabi Oncology Limited, India -	Due date (14-02-2017) Firm submitted fee of Rs.7500/-on 15-02-2012.As the renewal application is received late but within 60 days after expiry of Registration Differential fee 0f Rs32,500, paid on 01-04-2019 **for the regularization of renewal application of year 2012.**
2	044869	Adrim 50mg injection Each 25ml contains: Doxorubicin HCl…..50mg	15-02-2007 Change of manufacturer name 04-01-2010 Fresenius Kabi Oncology Limited, India	-do-
3	044870	Adrim 10mg injection Each 5ml contains: Doxorubicin HCl…..10mg	15-02-2007 Change of manufacturer name 04-01-2010 Fresenius Kabi Oncology Limited, India	**-do-**
4	044881	Intaxel 30mg Injection Each ml contains: Paclitaxel USP…..6mg **Manufactured by M/s Dabur Pharma Ltd,India**	15-02-2007 Change of manufacturer name 10-12-2009 Fresenius Kabi Oncology Limited, India	Due date (14-02-2017) Firm submitted fee of Rs.7500/-on 15-02-2012.As the renewal application is received late but within 60 days after expiry of Registration Differential fee 0f Rs32,500, paid on 01-04-2019 **for the regularization of renewal application of year 2012**
5	044882	Intaxel 100mg Injection Each ml contains: Paclitaxel USP…..6mg	Do	Due date (14-02-2017) Firm submitted fee of Rs.7500/-on 15-02-2012.As the renewal application is received late but within 60 days after expiry of Registration

		Manufactured by M/s Dabur Pharma Ltd,India		Differential fee 0f Rs32,500, paid on 01-04-2019 **for the regularization of renewal application of year 2012**
6	044872	Cytarine 500mg Injection Each ml contains: Cytarabine B.P….500mg **Manufactured by M/s Dabur Pharma Ltd,India**	15-02-2007 Change of manufacturer name 10-12-2009 Fresenius Kabi Oncology Limited, India	do
7	044871	Cytarine 100mg Injection Each ml contains: Cytarabine B.P….100mg **Manufactured by M/s Dabur Pharma Ltd,India**	do	do

Decision: Registration Board deferred the above cases for evaluation under Import Policy for Finished Drugs, however the renewal status shall be communicated to the concerned section for processing of post registration variation at their end.

a) M/s Quaper (Pvt) Ltd. Sargodha

Sr. No	Reg. No	Products/Name	Initial Date of Registration	Application receiving date and fee submitted date and due date
1	048932	Neuromin Tablet Each tablet contains: Mecobalamin …500mcg	06-02-2008	Due date (05-02-2018) Firm submitted fee of Rs.10,000/-on 06-02-2013.As the renewal application is received late but within 60 days after expiry of Registration Differential fee 0f Rs10,000, paid on 11-01-2019
2	048927	Quvin 250mg tablet Each tablet contains Levofloxacin…250mg	Do	Do
3	048928	Quvin500mg tablet Each tablet contains Levofloxacin…250mg	Do	Do
4	048931	Bifen100mg tablet Each tablet contain Flurbiprofen….100mg	Do	do
5	048933	Iropol tablet	Do	do
Decision:		**Registration Board acceded to the request of firm and decided to grant renewal w.e.f. 06-02-2018 to 05-02-2023.**		
b) Roche Pakistan Limited,Karachi				
1	027375	Xeloda tablets Each tablets contains : Capecitabine…500mg	09-08-2002 Registered in import M/s F.Hoffmann La- Roche Inc,USA for	Due date (08-08-2012) Firm submitted fee of Rs 7500 in year 2012 on 06-09-2012 .As the renewal application is received late but within 60 days after expiry of Registration. firm

			M/s F.Hofmann La-Roche Ltd, Switzerland Bearing statement **(Two year import then local manufacturing)**	submitted differential fee 40,000 on 05-03-2019 . Regularization by the Board is required.

Decision: Registration Board acceded to the request of firm and decided to regularize the renewal of year 2012 till 08-08-2017.

c) Derma Techno Pakistan,528 Sunder Industrial Estate Raiwind Road ,Lahore .Pakistan.

Sr. No.	Reg. No.	Product Name	Initial date of Registration	Application Receiving date
1	071267	Grower 5% Solution Each mi contains Minioxidil…….50mg	18-08-2011 Change of brand name "grower	**Due date (17-08-2016)** Firm submitted fee of Rs.10,000/-on 29-09-2016.As the renewal application is received late but within 60 days after expiry of Registration differential fee of Rs 10,000paid on 07-10-2016

Decision: Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 18-08-2016 to 17-08-2021.

With Prescribed Fee

a) M/s Medisynth Pharmaceuticals ,Isalambad

Sr. No.	Reg. No.	Product Name	Initial date of Registration	Application Receiving date
1	075223	Nuldep 20mg capsule Each capsule contains: Fluoxetine(as HCl)…20mg	13-03-2013	**Due date (12-3-2018)** Firm submitted fee of Rs.20,000/-on 11-05-2018.As the renewal application is received late but within 60 days after expiry of Registration
2	075222	Gabasyn 300mg Capsule Each capsule contains: Gabapentine…..300mg	13-03-2013	**-do-**

Decision: Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 13-03-2018 to 12-03-2023.

b) M/s WELL&WELL PHARMA (PVT) LIMITED PLOT7,STREET S-8 RRCI National Industrial Zone, Rawat

Sr. No.	Reg. No.	Product Name	Initial date of Registration	Application Receiving date
1	065119	Clarivel 250mg Each tablet contains Clarithromycin….250mg	22-07-2010	**Due date (21-07-2015)** Firm submitted fee of Rs.20,000/-on 24-08-2015.As the renewal application is received late but within 60 days after expiry of Registration
2	065120	Clarivel 500mg Each tablet contains Clarithromycin….500mg	do	**-do-**

Decision: Registration Board acceded to the request of firm and decided to grant the renewal w.e.f. 22-07-2015 to 21-07-2020.

Pak China International

Registration Board in its 284TH Meeting decided the case as follows that requires the correction mentioned in the last column

Sr. No.	Brand Name	Date of Reg.	Decision of the Board	Typographical Error
1.	Metronidazole injection 100ml Per single dose glass vial contains Metronidazole ….0.5gm	08-07-1992 Change of manufacturing site 17-02-2010 Change of exporter 11-02-2016	Registration Board grant renewal w.e.f. 17-02-2015 to 16-02-2020	correction in registration number Correct registration number is 013267 instead of 031121

Decision: Registration Board noted the above information.

Item No. IV Division of Biological Evaluation & Research

Sr. No.	Details of Applications	No. of Cases
A	Imported Human Biologicals from Reference Countries/ WHO PQ	2
B	Imported Human Biologicals from non- Reference Countries	2
C	Imported Veterinary Biologicals from Reference Countries	4
D	Miscellaneous/ Deferred cases	23
Additional Agenda		17
Total		48

Sr. No.	Assistant Director	Designated No.	No. of Cases
a.	Mr. Khurram Khalid	AD-I	8
b.	Mr. Saadat Ali Khan	AD-II	5
c.	Mr. M. Zubair Masood	AD-III	35

A: Imported Human-Biological from reference countries

1.	Name and address of Importer	M/s Novo Nordisk Pharma (Private) Limited, 113, Shahrah-e-Iran, Clifton, Karachi
	Detail of DSL	License No. 0354 dated 12-05-17 valid till 10-04-2019
	Name and address of Manufacturer	Product License Holder and Manufacturer: M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark
	Brand Name +Dosage Form + Strength	Norditropin NordiFlex 5mg/1.5ml Solution for Injection
	Diary No. Date of R& I & fee	Dy. No. 41193(R&I) dated 06-12-2018 Rs. 50000/- dated 05-12-2018
	Composition	Each ml of solution contains: Somatropin……3.3mg
	Pharmacological Group	Recombinant Growth Hormone
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. Specifications
	Shelf Life	02 years
	Document Details	Valid legalized CoPP No. 2018080406 dated 03-08-2018 valid for two years issued by Danish Medicines Agency.
	Pack size & Demanded Price	1's PFS/ Not Provided
	International Availability	Argentina, Austria, Australia etc.
	Products already registered in Pakistan	Norditropin of M/s Novo Nordisk.
	Remarks of the evaluator	
Decision:	**Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Danish Medicine Agency (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**	
2.	Name and address of Importer	M/s Novo Nordisk Pharma (Private) Limited, 113, Shahrah-e-Iran, Clifton, Karachi
	Detail of DSL	License No. 0354 dated 12-05-17 valid till 10-04-2019
	Name and address of Manufacturer	Product License Holder and Manufacturer: M/s Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd, Denmark
	Brand Name +Dosage Form + Strength	Norditropin NordiFlex 10mg/1.5ml Solution for Injection
	Diary No. Date of R& I & fee	Dy. No. 41192(R&I) dated 06-12-2018 Rs. 50000/- dated 05-12-2018
	Composition	Each ml of solution contains: Somatropin……6.7mg
	Pharmacological Group	Recombinant Growth Hormone
	Type of Form	Form-5A
	Finished Product Specification	Ph. Eur. Specifications
	Shelf Life	02 years
	Document Details	Valid legalized CoPP No. 2018080407 dated 03-08-2018 valid for two years issued by Danish Medicines Agency.
	Pack size & Demanded Price	1's PFS/ Not Provided
	International Availability	Argentina, Austria, Australia etc.
	Products already registered in Pakistan	Norditropinof M/s Novo Nordisk.
	Remarks of the evaluator	
Decision:	**Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Danish Medicine Agency (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 S. Ejazuddin & Co., Zia Plaza, Altaf Hussain Road, Karachi
	DSL Detail	License No. 0385 dated 08-08-2017 valid till 01-04-2019
	Name of Manufacturer	M/s Changzhou Qianhong Bio-pharma Co., Ltd., 192, Huanghe West Road, Xinbei District, Changzhou, Jiangsu, China
	Brand Name +Dosage Form + Strength	**Asparaginase (Escherichia) for Injection 10000U**
	Composition	Each vial contains: Asparaginase (Escherichia)……. ……10000U
	Finished product specifications	Chinese Pharmacopoeia
	Pharmacological Group	Anti-neoplastic agent
	Shelf life	2 years
	International availability	Elspar of M/s Lundbeck, USA
	Products already registered in Pakistan	Asparaginase 10000 Medac of M/s Premium Pharma, Karachi
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 277 Dated 07-03-2016 Rs. 100000/- Dated 07-03-2016
	Demanded Price / Pack size	1's Vial/ Rs. 7835.25/-
	General documentation	Valid Legalized CoPP No. 2016010 dated 20-12-2016.
	Remarks of Evaluator	Even after two deficiency letters, the firm did not submitted the following: a. Drug Product Specification data in light of decision of 267th meeting. b. Clinical trial data.
	Decision: Registration Board deferred the case and gave last chance to the firm to submit the following documents or their application will be rejected: **a. Drug Product Specification data in light of decision of 267th meeting.** **b. Clinical trial data.**	
2.	Name of Importer	M/s Sindh Medical Store, Sector 13B/B-10 Block-6 PECHS, Karachi
	DSL Detail	License No. 0873 dated 07-02-2019 valid till 01-07-2020
	Name of Manufacturer	M/s SK biosciences Co., Ltd., 150 Saneopdanji-gil, Pungsan-eup, Andong-siGyeongsangbuk-do, Republic of Korea
	Brand Name +Dosage Form + Strength	**SkyCell Flu Quadrivalent Prefilled syringe (surface antigen, inactivated, prepared in cell cultures)**
	Composition	Each (0.5ml) PFS contains: The composition of flu vaccine varies on year to year basis as per WHO recommendation, thus following composition will change according to the importing year receomendations: Purified inactivated influenza virus surface antigen [A/Michigan/45/2015, NYMC X-275 (H1N1)]……..15µg Purified inactivated influenza virus surface antigen [A/Singapore/INFIMH-16-0019/2016, IVR-186 (H3N2)]……..15µg Purified inactivated influenza virus surface [B/Maryland/15/2016]……..15µg Purified inactivated influenza virus surface [B/Phuket/3073/2013]……..15µg
	Finished product specifications	Ph. Eur. Specifications

	Pharmacological Group	Human Vaccine
	Shelf life	12 months
	International availability	Malaysia
	Products already registered in Pakistan	Approved by Registration Board, pricing is under process.
	Type of Form Dy. No & Date of application, Fee submitted	Form-5A Dy. No. 1382(R&I) dated 11-01-2019 Rs. 100000/- dated 20-12-2018
	Demanded Price / Pack size	1's PFS (0.5ml)/ Rs. 1947.60/-
	General documentation	Valid legalized CoPP No. 2018-A1-1491 dated 20-09-2018
	Remarks of Evaluator	The composition of flu vaccine varies on year to year basis, when supplied it will be according to the WHO recommended candidate vaccine compositionas available on official website: https://www.who.int/influenza/vaccines/virus/candidates_reagents/summary_b_vic_cvv-egg_nh1819.pdf?ua=1
	Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.	

C: Imported Veterinary Biologicals from reference countries.

1.	**Name of Importer**	M/s. Ghazi Brothers Address: Ghazi House, D-35, K.D.A Scheme No.1, Miran Muhammad Shah Road Karachi-75350, Pakistan
	DSL details	Copy of DSL Address: M/s. Ghazi Brothers, Ghazi house D-35, K.D.A Scheme No.1 Miran Muhammad Shah Road Karachi. Godown Address: B-32 Al Hilal Society KDA Scheme NO.7, Karachi. Plot No. 335/15 DehTuppuKorangi. Validity : 25-May-2020 Status: License to sell drugs by way of wholesale
	Name of Manufacturer	M/s. IDT Biologika GmbH Address: Am Pharmapark D-06861 Dessau-Rosslau Germany
	Brand Name +Dosage Form + Strength	SALMOVAC 440 (Freeze-dried live *Salmonella enteritidis* Vaccine)
	Composition	Each Dose of vaccine contains (At least): Double-attenuated (adenine-histidine auxotrophic) *Salmonella enteritidis* mutant, strain 441/014 ≥ 1x 10^8CFU
	Finished product specifications	Innovator
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (after reconstitution according to directions:4 hours)
	International availability	Not Provided.
	Products already registered in Pakistan	The exact strain is not available in Pakistan as per our record but organism wise (*Salmonella enteritidis*) following vaccines are already registered. **AviPro Salmonella Vac E** (Live *Salmonella enteritidis*, Strain Sm24/Rif12/Ssq at least…….1 x108.0CFU) by Golden Harvest Karachi
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. (R&I) Dated 25 October 2018 Rs. 50,000/- 25 October 2018
	Demanded Price / Pack size	Decontrolled/ 1000 & 5000 doses

	General documentation	*Original Legalized Certificate of Pharmaceutical Product (COPP):* Issued by:SACHSEN-ANHALT LANDESVERWALTUNGSAMTVERBRAUCHERSCHUTZ, VETERINARANGELEGENHEITEN DESSAUER STRABE 70 06118 HALLE/SAALE DEUTSCHLAND Translation**:**Saxony-Anhalt State administration office consumer protection, veterinary affairs dessauerstrabe70 06118 Halle / Saale Germany. • Certificate No: 005/2018 • Issued on: 13-July-2018 *Original Legalized GMP Certificate:* • Issued by: As mentioned above • Certificate No.: DE/15/001/2017 Issued on: 06-February-2017 valid for 3 years.
	Remarks of Evaluator	
Decision: Registration Board referred the case to Expert Working Group on Veterinary Drugs for evaluation of strain.		
2	Name of Importer	M/s. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II, Ali Tower, M.M Alam Road, Gulberg, Lahore
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Avda. La Selva, 135 17170 Amer (Girona) Spain
	Brand Name +Dosage Form + Strength	HIPRABOVIS SOMNI/Lkt Bovine Injectable Emulsion
	Composition	Composition per dose (2 ml): *Mannheimiahaemolytica* Biotype A serotype A1, inactivated cell free suspension containing Leukotoxoid: ELISA……> 2.8(*)/dose Inactivated *Histophilussomni*Bailie strain: MAT…… > 3.3 (**)/dose (*)A minimum of 80% of vaccinated rabbits show ELISA value of > 2.0; the mean ELISA is > 2.8. (**)A minimum of 80% of vaccinated rabbits show a $\log_2$ MAT value of > 3.0; the mean $\log_2$ MAT > 3.3.
	Finished product specifications	Innovator
	Pharmacological Group	Inactivated bacterial vaccine (Cattle vaccine)
	Shelf life	18 months at 2-8^{0}C
	International availability	Spain
	Type of Form Dy No & Date of application, Fee submitted	Form 5-A, Dy. No. 22409(R&I) Date: 27-06-2018 Rs. 100,000/- Date: 27-06-2018
	Demanded Price / Pack size	Decontrolled/10Doses & 50Doses
	General documentation	Legalized COPP dated 11-12-2017, Issued by: Departamento de medicamentosveterinarios de la Agencia Espanola de Medicamentos y ProductosSanitarios Translation: Department of veterinary medicines of the Spanish Agency of Medicines and Health Products
	Remarks of Evaluator	

Decision:	**Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of Spanish Agency of Medicines and Health Products (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**	
3.	Name of Importer	M/s Saadat International, 117-Habitat Appartments, Shadman-II, Jail Road, Lahore.
	DSL details	License No. 21-A/DGBT/11/2014 valid till 19-06-2018
	Name of Manufacturer	M/s Merial, Inc. 1168 Airport Parkway, SW, Gainesville, GA 30501-6816
	Brand Name +Dosage Form + Strength	BDA Blen Bursal Disease Vaccine, Live Virus
	Composition	Each dose of vaccine contains the following through expiration: Infectious Bursal Disease Virus, 2512 strain, at least……$100EID_{50}$ Bursal Disease Viral Antiserum, at least……..24 units
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months
	International availability	USA
	Products already registered in Pakistan	BDA Blen in 25x1000doses pack
	Type of Form Dy. No.& Date of application, Fee submitted	Form-5A Initial Dy. No. 1393(R&I) dated 29-11-2016 Deficiency Completion Dy. No. 3040(R&I) dated 09-04-2019 Rs. 100000/- dated 29-11-2016
	Demanded Price / Pack size	25's Vials x 2000 doses
	General documentation	Valid Legalized Certificate of Licensing and Inspection No. 19-00426 dated 10-12-2018.
	Remarks of Evaluator	The firm has submitted real time stability data of 01 batch for 24 months of 2000 doses. The manufacturer submitted that the stability studies were conducted in the USA based on the 9CFR guideline. As per 9CFR 114.13, USDA does not require stability testing on multiple dose presentation for registered products only one dose presentation must be tested. Moreover, this stability studies are the only available data that support the 2000dose and 8000 dose, the same data was used to register all the pack sizes in the country of origin.
Decision:	**Keeping in view valid legalized Certificate of Licensing and Inspection indicating product availability in country of origin and approval of USDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.**	
4.	Name of Importer	M/s Saadat International, 117-Habitat Appartments, Shadman-II, Jail Road, Lahore.
	DSL details	License No. 21-A/DGBT/11/2014 valid till 19-06-2018
	Name of Manufacturer	M/s Merial, Inc. 1168 Airport Parkway, SW, Gainesville, GA 30501-6816
	Brand Name +Dosage Form + Strength	BDA Blen Bursal Disease Vaccine, Live Virus
	Composition	Each dose of vaccine contains the following through expiration: Infectious Bursal Disease Virus, 2512 strain, at least……$100EID_{50}$ Bursal Disease Viral Antiserum, at least……..24 units
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine

	Shelf life	24 months
	International availability	USA
	Products already registered in Pakistan	BDA Blen in 25x1000doses pack
	Type of Form Dy. No.& Date of application, Fee submitted	Form-5A Initial Dy. No. 1393(R&I) dated 29-11-2016 Deficiency Completion Dy. No. 3040(R&I) dated 09-04-2019 Rs. 100000/- dated 29-11-2016
	Demanded Price / Pack size	15's Vials x 8000 doses
	General documentation	Valid Legalized Certificate of Licensing and Inspection No. 19-00426 dated 10-12-2018.
	Remarks of Evaluator	The firm has submitted real time stability data of 02 batches for 24 months of 8000 doses. The manufacturer submitted that the stability studies were conducted in the USA based on the 9CFR guideline. As per 9CFR 114.13, USDA does not require stability testing on multiple dose presentation for registered products only one dose presentation must be tested. Moreover, this stability studies are the only available data that support the 2000dose and 8000 dose, the same data was used to register all the pack sizes in the country of origin.
Decision: Keeping in view valid legalized Certificate of Licensing and Inspection indicating product availability in country of originand approval of USDA (Reference Regulatory Authority); Registration Board approved the productsubject to compliance of current Import Policy for finished drugs.		

E: Miscellaneous/ Deferred Cases

1. Imported Human Biological Lahore from non-reference countries applied by M/s. 3A Diagnostics, deferred in 286th meeting of Registration Board.

Following product of M/s 3A Diagnostics, Lahore was deferred in 286th meeting of Registration Board as per following details:

Name of Importer	**M/s. 3A Diagnostics** 12-F-1, MehmoodChowk, Main Johar Town, Lahore
DSL details	Copy of valid DSL no. 05-352-0066-034496D valid up to05-0-07-2020
Name of Manufacturer	**YuxiWalvax Biotechnology Co., Ltd** 83, South Dongfeng Road, High & new Technology Industries Development Zone, Yuxi, Yunnan Province, P.R. China
Brand Name +Dosage Form + Strength	**SALBEKSON** Diphtheria, Tetanus and Acellular Pertussis Combined Vaccine, adsorbed, for injection. 0.5mL vial
Composition	Each 0.5mL vial contains: Acellular pertussis…….. not less than 4IU Diphtheria toxoid..…….. not less than 30IU Tetanus toxoid……..…….. not less than 40IU
Finished product specifications	European Pharmacopeia
Pharmacological Group	Human vaccine
Shelf life	24 months
International Availability of this product	China
Similar Product already registered in Pakistan	Diphtheria tetanus and pertussis vaccine adsorbed by M & M Pharma Lahore.
Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy.No.23591 dated 09-07-2018 Rs.100,000/- dated 29-06-2018.
Demanded Price/ Pack size	PKR 1330/vial
General documentation	1. Legalized Free Sale Certificate issued No.2017-42 by Yunnan Food and Drug Administration, China dated 31-07-2017. 2. Legalized Certificate of Pharmaceutical Product issued No.2017-047 by Yunnan Food and Drug Administration, China dated 31-07-2017. 3. Legalized GMP Certificate issued No.CN20150168 by China Food and Drug Administration dated 30-10-2015. 4. Original Letter of Authorization dated 6-06-2017. Pharmaceutical Product (CoPP) issued on 17-05-2017.
Decision of Registration Board 286th meeting	*Registration Board deferred the application for clarification of following by the firm:* *a. Only 20 individuals are used for efficacy studies which is very low number of subjects.* *b. Efficacy studies are single centered instead of multi-center.*
Remarks of evaluator	1. Submitted for correction in previous decision in *clause a* for <u>safety studies instead of efficacy studies.</u> 2. Stability data as described earlier. 3. In addition to previously submitted data, the firm has submitted multi-centered, double blinded clinical data for 750 patients.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the productsubject to compliance of current Import Policy for finished drugs.	

2. Veterinary vaccine applied by M/s Forward Solutions Pakistan, deferred in 286th meeting of Registration Board.

Following product of M/s Forward Solutions Pakistan, Lahore was deferred in 286th meeting of Registration Board as per following details:

Name of Importer	**M/s. Forward Solutions Pakistan** Plot No.19-B. Qazalbash Chowk Abdul Sattar Edhi Road, District Lahore.
Name of Manufacturer	**Manufacturer:** M/s FATRO S.P.A Via Molino Emili, 2 – 25030 Maclodio (BS) – Italy **Product License Holder:** M/s FATRO S.P.A Via Emilia, 285 – 40064 Ozzano Emilia (Bologna) Italy
Brand Name +Dosage Form + Strength	**IBA-VAC** Freeze-dried vaccine for oral suspension
Composition	Each dose (0.3mL/bird) contains; Live attenuated virus of infectious bursal disease I-65PV strain Titre: not less than 10^3EID_{50}
Finished product specifications	B.P
Pharmacological Group	Veterinary
Shelf life	18 Months
Similar Product already registered in Pakistan	Bio Gumboro Vaccine (Live Freeze Dried I/65/Pv Vaccine Against IBD) by Khyber Poultry Enterprises Faisalabad.
Type of Form Dy No & Date of application, Fee submitted	Form-5A R&I Dy.No. 24240 dated 16-07-2018 AD Bio Dy. No. 906 dated 16-07-2018. Rs.100,000/- dated 20-6-2017(the fee was submitted for 2500 doses which was not processed upon firm's request and it was further requested to consider the said fee for 5000 doses)
Demanded Price/ Pack size	Decontrolled/ Pack of 5000 doses
General documentation	Legalized Certificate of Pharmaceutical Product (CoPP) having Certificate No.86/2018/C issued by Ministry of Health, Directorate General for Animal Health and Veterinary Medicinal Products, Italy.
Decision of Registration Board in 286th meeting	*Registration Board deferred the application for clarification regarding the difference in volume of water required for dilution of vaccine according to the age and submitted dose i.e. 0.3ml/bird.*
Remarks of evaluator	The firm has submitted revised Form 5A and informed that dose is 10mL/bird i.e. 10^3EID_{50}/10mL and wrong dose was mentioned on previous Form 5A. Clarifications is as under • 1 dose of vaccine/10mL of water for 1 bird. • 5000 doses of vaccine/50,000mL (50L) of water for 5000 birds The same dosage was already mentioned in summary of product characteristics submitted with initial application.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the productsubject to compliance of current Import Policy for finished drugs.	

3. Human vaccine applied by M/s. Amson Vaccine & Pharma Pvt Ltd, deferred in 287th meeting of Registration Board;

Following product of M/s Amson Vaccines & Pharma Pvt. Ltd., Islamabad was deferred in 287th meeting of Registration Board as per following details:

Name of Importer	**M/s. Amson Vaccine & Pharma Pvt Ltd** 115, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
Name of Manufacturer	**M/s Panacea Biotec Limited (Vaccine Division),** Unit-II, Malpur, Baddi, Distt. Solan (HP)-173205, India
Brand Name +Dosage Form + Strength	**Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral), [bOPV],** Bulk Source: PT. BioFarma, Indonesia 20 doses (2mL) Vial
Composition	Each 0.1mL (2 drops) contains: Poliovirus Type 1 (Sabin strain).....NLT $10^{6.0}$ $CCID_{50}$ Poliovirus Type 3 (Sabin strain).....NLT $10^{5.80}$ $CCID_{50}$
Finished product specifications	Manufacturer Specifications
Approval status of this product in Reference countries	NA
Pharmacological Group	Oral Vaccine
Shelf life	24 Months (at -20^0C)
International Availability of this product	INDIA
Similar Product already registered in Pakistan	bOPV by M/s. Amson Vaccine & Pharma Pvt Ltd, Islamabad.
Type of Form Dy No & Date of application, Fee submitted	Form 5-A dated 26-6-2018 R&I Dy.No.23590 dated 09-07-2018. Rs.100,000/- dated 05-07-2018.
Demanded Price/ Pack size	4USD per 20 dose vial/ 2mL vial of 20 Doses
General documentation	Legalized CoPP No. MB/07/632/WHO GMP/18-19 valid upto 25thSeptember, 2020.
Decision of Registration Board	*Registration Board deferred the case for submission of following by the firm:* *a. Real time stability data of 24 months.* *b. Clarification regarding manufacturer's specifications mentioned in form-5A while product is available in BP.*
Remarks of Evaluator (**Khurram Khalid AD**)	The firm has submitted a. The required stability data for 24 months. b. Demanded BP specifications WHO PQ Status: https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=335
Decision: Keeping in view WHO Prequalification and legalized CoPP indicating productavailability in country of origin; Registration Board approved the product subject to compliance ofcurrent Import policy for finished drugs.	

4. Information regarding withdrawal of "*application for registration of Lartruvo 500mg/50ml (10mg/ml) Concentrate for solution for infusion*" applied by M/s Eli Lilly Pakistan (Private) Limited, Karachi:

Following products of M/s Eli Lilly Pakistan (Private) Limited, Karachi were approved in 275th meeting of Registration Board as per following details:

Name of Manufacturer	**Brand Name & Composition**	**Document details (CoPP)**	**Decision of RB in 275th meeting**
Product License Holder: M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.	Lartruvo 500mg/50ml (10mg/ml) Concentrate for	Legalized CoPP No 02/17/111515 issued on 04-08-	*Keeping in view valid legalized CoPP and approval of European Medicine Agency (EMA)*

Name of Manufacturer: M/s Eli Lilly and company, Lilly Corporate Center, Indianapolis, Indiana 46285, USA **Site responsible for batch release in the EU, quality control and secondry packaging:** M/s Lilliy S.A., Avda. De la Industria 30, Alcobendas, 28108 Madrid, Spain. **Site responsible for quality control:** M/s ImClone Systems LLC, 33 ImClone Drive, Branchburg, NJ 08876, USA.	solution for infusion Each ml of concentrate for solution for infusion contains: Olaratumab…10mg Shelf Life: 2 years at 2-8^{o}C.	2017.	*(Reference Regulatory Authority); Registration Board approved the product subject to price fixation by the Federal Government and compliance of current Import Policy for Finished Drugs.*

The price of aforementioned product has been fixed vide SRO 1609(I)/2018 dated 31-12-2018 as per following details:

Brand Name & Composition	Pack Size	Approved M.R.P
Lartruvo 500mg/50ml (10mg/ml) Concentrate for solution for infusion Each ml of concentrate for solution for infusion contains: Olaratumab…10mg	50ml Vial x 1's	Rs. 142,820 (originator Brand)

M/s Eli Lilly and Company applied for withdrawing the pending application for Lartruvo (Olartumab) for the treatment of soft tissue sarcoma due to the recently disclosed Phase 3 clinical trial (ANNOUNCE) results. Specifically, ANNOUNCE did not confirm the clinical benefit of Lartruvo in combination with doxorubicin as compared to doxorubicin, a standard of care treatment. The study did not meet the primary end points to prolong survival in the overall population or in the leiomyosarcoma (LMS) sub-population. Lartruvo was well tolerated; there were no new safety signals identified and the safety profile was comparable between treatment arms

Decision: Registration Board deferred the case for confirmation, of status of product registration in other reference regulatory authorities, by the firm.

5. Change in market authorization holder and manufacturer applied by M/s Eli Lilly Pakistan (Private) Limited, Karachi:

M/s Eli Lilly Pakistan (Private) Limited, Karachi applied for the change in market authorization holder and manufacturer of their already registered human biologicals as per following details:

Sr. No.	Reg. No.	Brand Name & Composition	Already approved Market Authorization Holder & Manufacturer	Newly Applied Market Authorization Holder & Manufacturer
1.	089812	Basaglar Solution for injection in Cartridge Each ml contains: Insulin Glargine….100units	M/s Eli Lilly Regional Operations GmbH, kolblgasse 8-10, 1030 vienna, Austria. M/s Lilly France, 2 rue	M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands M/s Eli Lilly Italia S.p.A., Via Gramsci 731-733, 50019 Sesto Fiorentino, (FI),

			du Colonel Lilly, 67640 Fegersheim, France (also responsible for batch release in the EU, quality control, primary and secondary packaging)	Italy.(also responsible for batch release in the EU, quality control, primary and secondary packaging)
2.	089813	Basaglar Solution for injection in prefilled pen (kwikpen) Each ml contains: Insulin Glargine….100units		M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands M/s Eli Lilly Italia S.p.A., Via Gramsci 731-733, 50019 Sesto Fiorentino, (FI), Italy (also responsible for batch release in the EU, quality control& primary packaging) & M/s Lilly France, 2 rue du Colonel Lilly, 67640 Fegersheim, France (Site responsible for batch release in the EU, quality controland secondary packaging)

The firm has submitted the following documents for each product:

a. Application on Form-5A.
b. Fee Challan of Rs. 100000/- for each product
c. Copies of Initial registration letters dated 25-05-2018.
d. Valid legalized CoPPs vide no. 01/19/129645 and 01/19/129646 dated 31-08-2018 for cartridge and kwikpen respectively.
e. A declaration that no sole agency agreement between Eli Lilly to Eli Lilly.
f. A declaration that no contract between Eli Lilly Netherlands and Eli Lilly Italy.
g. An undertaking that the provided information/ documents are true/ correct to the best of their knowledge.

The applications of the firm have been evaluated as per SOPs established in 283rd meeting of Registration Board. The firm has submitted same accelerated and long-term stability data for *Basaglar Cartridge & Kwikpen* and clarified as under;

'The accelerated stability data already provided refer to the product packaged in its primary container closure system. The purpose of accelerated studies is to determine a stress that simulates the entire validity period of the product from a chemical degradation point of view. Since the secondary packaging, and in the same way the pen, is not designed to protect the product, the accelerated studies on nude cartridges are representative of the product packaged both in blister and in KwikPen.

Concerning long-term studies, according to module 3.2.R.3 Medical Device – Prefilled Pen – Injector, paragraph III. Drug Stability, the stability of the drug product has been established in the primary container closure system (the cartridge) therefore long-term data already provided are representative also for the KwikPen.'

Decision: Keeping in view the approval of EMA (Reference Regulatory Authority); Registration Board approved the change in market authorization holder and manufacturer as per following details:

Sr. No.	Reg. No.	Brand Name & Composition	Already approved Market Authorization Holder & Manufacturer	Newly Approved Market Authorization Holder & Manufacturer
1.	**089812**	**Basaglar 100units Cartridge**	**M.A. holder: M/s Eli Lilly Regional Operations**	**Market AuthorizationHolder: M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands**

			GmbH, kolblgasse 8-10, 1030 vienna, Austria. **Manufacturer:** **M/s Lilly France, 2 rue du Colonel Lilly, 67640 Fegersheim, France (also responsible for batch release in the EU, quality control, primary and secondary packaging)**	**Manufacturing Site:** **M/s Eli Lilly Italia S.p.A., Via Gramsci 731-733, 50019 Sesto Fiorentino, (FI), Italy.(also responsible for batch release in the EU, quality control, primary and secondary packaging)**
2.	**089813**	**Basaglar 100units Kwikpen**		**Market Authorization Holder:** **M/s Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands** **Manufacturing and Primary Packaging Site:** **M/s Eli Lilly Italia S.p.A., Via Gramsci 731-733, 50019 Sesto Fiorentino, (FI), Italy (also responsible for primary packaging)** **Secondary Packaging & Batch Release Site:** **M/s Lilly France, 2 rue du Colonel Lilly, 67640 Fegersheim, France**

6. Applications of M/s Huzaifa International, Sargodha deferred in various meeting of Registration Board.

Following product of M/s Huzaifa International, Sargodha were deferred in 266th meeting of Registration Board for the expert opinion of Dr.Qurban Ali. The detail of the product as under:

Manufacturer	Brand Name & Composition	Type of Form Dy No & Date of application Fee submitted Pack size/ Demanded Price	Document details (CoPP) Me too status/New molecule	Decision
Komipharm International Co., Ltd. 17, Gyeongje-Ro, Siheung-Si, Gyeonggi-Do, The republic of Korea	PRO-VAC™ FP (lyophilized part) Each dose (0.5ml) contains: TCH Fowl Pox Virus Culture……50% SPGG…….50% (Diluent) Each 1000 ml contains: Nacl....8g KCl....0.2g Na_2HPO_4. $2H_2O$....2.6g KH_2PO_4....0.2g Phenol red...q.s. Distilled water....up to 1000ml	Form 5-A 118-ADC(BD) 06-12-2016 1495 30-11-2016 Rs. 100000/-24-10-2016 Pack: 1's (1000doses) Diluent 10ml vial	Legalized GMP Legalized Free Sale The diluent is also a part of pack composition; the firm has submitted Rs. 100000/- fee for the registration of diluent.	Deferred for evaluation of strain by Dr. Qurban Ali, Member Registration Board.

The expert opinion of Dr.Qurban Ali, Member Registration Board has been received and he has recommended the product for registration and use for protection and prophylaxis against FPV. .The expert opinion is reproduced as under:

"Kindly refer 266th Meeting of Registration Board on the subject noted above and please find below technical comments on the subject cited [PRO-VAC™FP(lyophilized part) TCH Fowl Pox], as follows:

Poxvirus diseases of poultry and other domestic birds have significant economic impact worldwide with losses resulting in the form of drop in egg production in layers, reduced growth rates in broilers, and in some cases death. The FPV is double-stranded DNA (260 to 309 kbp)

virus and infects chicken turkeys and other birds. Two forms of disease are associated with different routes of infection. The most common is the cutaneous form and the second diphtheric form. Prognosis with the second form of the disease is poor because lesions often cause death by asphyxiation. Vaccination programs in poultry and other birds vary widely, depending on several maternal immunity, vaccines available, costs and potential losses). Vaccination with live attenuated and non-attenuate viruses is used to control this disease.

The under consideration vaccine product is PRO-VAC^{TM}FP (lyophilized part) Fowl Pox(TCH strain). The strain is already registered in combination (AE+FP) from the same manufacturer. The PRO-VAC^{TM}FP is a product from Animal Health Division Komipharm, S.Korea and is recommended for registration and use for protection and prophylaxis against FPV."

Decision: **Keeping in view recommendation of veterinary expert, valid legalized GMP and valid legalized FSC indicating productavailability in country of origin; Registration Board approved the product subject to compliance ofcurrent Import policy for finished drugs.**

7. Change of address of manufacturing site without change in location of already registered human biologicals applied by M/s RG Pharmaceutica (Pvt.) Ltd., Karachi.

M/s RG Pharmaceutica (Pvt.) Ltd., Karachi applied for the change in address of manufacturer of following registered biologicals without any change in actual manufacturing site as per following details:

Sr. No.	Reg. No.& Date	Brand Name & Composition	Already Approved Manufacturing site	Newly Applied Manufacturing site
1.	070928 11-06-2011	Ferti M Injectable Each vial contains: Menotropin (HMG)……75IU	M/s Livzon (Group) Pharmaceutical Factory, No. 38, Chuangye Road North, Liangang Industrial Zone, Zhuai, Guandong, China	M/s Livzon (Group) Pharmaceutical Factory, No. 38, Chuangye Road North, Jinwan District, Zhuai, Guangdong, China
2.	070929 11-06-2011	Ferti M Injectable Each vial contains: Menotropin (HMG)……150IU		
3.	070930 11-06-2011	Ferti C Injectable Each vial contains: Human Chorionic Gonadotrophin(HCG)…1000IU		
4.	070931 11-06-2011	Ferti C Injectable Each vial contains: Human Chorionic Gonadotrophin(HCG)…5000IU		

The firm has submitted the following documents:

a. Fee Challan of Rs. 5000/- for each product
b. Copy of copy of last renewal submissions.
c. Copy of approval letter of manufacturing site change for products at sr. no. 1-4 of above table dated 14-09-2018
d. Valid legalized GMP certificate No. GD20170764 dated 04-12-2017 valid till 03-12-2022 of new manufacturing address

e. Valid legalized CoPPs No. ZH18-031, ZH18-032, ZH18-033, & ZH18-034 dated 01-11-2018 for Ferti-M Injection 75IU, Ferti-M Injection 150IU, Ferti-C Injection 1000IU and Ferti-C Injection 5000IU respectively issued by Zhuai FDA.
f. Valid legalized approval of Drug Supplementry application dated 30-11-2015 issued by Guangdong FDA indicating that the address is changed without any change in the actual manufacturing site.

The last renewal application submissions have been verified from R&I section of DRAP and the firm has submitted the yellow copies of fee challans.

Decision: **Keeping in view the valid legalized CoPPs and approval of country of origin; Registration Board approved the change in manufacturing site address from M/s Livzon (Group) Pharmaceutical Factory, No. 38, Chuangye Road North, Liangang Industrial Zone, Zhuai, Guandong, China to M/s Livzon (Group) Pharmaceutical Factory, No. 38, Chuangye Road North, Jinwan District, Zhuai, Guangdong, China without change in the actual manufacturing site of Ferti M 75IU (Reg. No. 070928), Ferti M 150IU (Reg. No. 070929), Ferti C 1000IU (Reg. No. 070930) and Ferti C 5000IU (Reg. No. 070931).**

8. Change of manufacturing site of already registered Solvent Isotonic for Ferti-C and Ferti-M Injections applied by M/s RG Pharmaceutica (Pvt.) Ltd., Karachi.

M/s RG Pharmaceutica (Pvt.) Ltd., Karachi applied for the change in manufacturing site of Solvent Isotonic for Ferti-C and Ferti-M Injections as per following details:

Sr. No.	Reg. No.& Date	Brand Name & Composition	Already Approved Manufacturing site	Newly Applied Manufacturing site
5.	070993 22-06-2011	Solvent- Isotonic for Ferti-C &Ferti-M Injections Each 2ml vial contains: Sodium Chloride……..19.35mg	M/s Livzon (Group) Pharmaceutical, Zhuai, Guandong, P.R. China	M/s Livzon (Group) Pharmaceutical Factory, No. 38, Chuangye Road North, Jinwan District, Zhuai, Guangdong, China

The firm has submitted the following documents:

a. Application on form-5A
b. Fee Challan of Rs. 100000/-
c. Copy of copy of last renewal submissions.
d. Valid legalized GMP certificate No. GD20170764 dated 04-12-2017 valid till 03-12-2022 of new manufacturing address
e. Valid legalized CoPPs No. ZH18-031, ZH18-032, ZH18-033, & ZH18-034 dated 01-11-2018 for Ferti-M Injection 75IU, Ferti-M Injection 150IU, Ferti-C Injection 1000IU and Ferti-C Injection 5000IU respectively issued by Zhuai FDA indicating saud diluent.

In this context, it is submitted that the firm initially applied for change in manufacturing site of lyophilized Ferti-C and Ferti-M injections from M/s Livzon (Group) Pharmaceutical, Zhuai, Guangdong, P.R. China to M/s Livzon (Group) PharmaceuticalFactory, No.38, ChuangyeRoadNorth, Liangang Industrial Zone,Zhuhai, Guangdong, China. Accordingly, the approval was granted and letter was issued after inspection of manufacturer abroad and now the firm has applied for change in address of manufacturer of these lyophilized injections without any change in actual manufacturing site. The firm submitted that they did not applied for the change in manufacturing site of this Solvent Isotonic and hence did not get the approval. Now, the firm has applied for change in manufacturing site with new address of site.Moreover, the

firm submitted that there is typographical error in initial registration letter of solvent regarding the name and composition as per following details:

Incorrect Brand Name & Composition	Correct Brand Name & Composition
Solvent- Isotonic for Ferti-C &Ferti-M Injections Each 2ml vial contains: Sodium Chloride…….. …..19.35mg	Sodium Chloride Injection Each 2ml vial contains: Sodium Chloride…….. …..18mg

The last renewal application submission has been verified from R&I section of DRAP and the firm has submitted the yellow copy of fee challan.

Decision: **Keeping in view the valid legalized CoPPs and the fact that solvent will be imported in combo pack; Registration Board approved the change in manufacturing site from M/s Livzon (Group) Pharmaceutical, Zhuai, Guandong, P.R. China to M/s Livzon (Group) Pharmaceutical Factory, No. 38, Chuangye Road North, Jinwan District, Zhuai, Guangdong, China for Solvent- Isotonic for Ferti-C &Ferti-M Injections (Reg. No. 070993) subject to compliance of current Import Policy for finished drugs. Registration Board also approved the correction in initial registration letter as per following details:**

Reg. No.	Incorrect Brand Name & Composition	Correct Brand Name & Composition
070993	**Solvent- Isotonic for Ferti-C &Ferti-M Injections** **Each 2ml vial contains:** **Sodium Chloride…….. …..19.35mg**	**Sodium Chloride Injection** **Each 2ml vial contains:** **Sodium Chloride……..……..18mg**

9. Imported Veterinary Biologicals applied by M/s Saadat International, Lahore deferred in 274th meeting.

Following product of M/s Saadat International, Lahore was deferred in 274th meeting of Registration Board as per following details:

Name of Importer	**M/s Saadat International,** **117-Habitat Appartments, Shadman-II, Jail Road, Lahore.**
DSL Details	License No. 21-A/DGBT/11/2014 valid till 19-06-2018
Name of Manufacturer	M/s Merial, Inc 1168 Airport parkway, SW Gainesville, GA 30501 USA.
Brand Name	PREVEXXION RN Marek's Disease Vaccine, Serotype 1, Live Herpesvirus Chimera
Composition	Frozen form: Each of vaccine contains the following through expiration: Marek's disease virus, serotype 1, RN1250 strain, at least……952 pfu Calf Serum……15% *DMSO/ Freezing Solution……..7.5% Freezing media…… q.s to 1 dose *DMSO: Dimethylsulfoxide
Finished product specifications	Manufacturer Specs (USDA 9CFR)
Pharmacological Group	Veterinary Vaccine
Shelf life	18 months
Approval status in reference countries	United States of America
Products already registered in Pakistan	Not Available
Type of Form	Form-5A

Dy No & Date of application Fee submitted	Dy. No. 9974 (R&I)Dated 25-07-2017 Rs. 100000/- Dated 25-07-2017
Pack size	2000doses, glass ampoule
General documentation	Legalized GMP certificate no. 1701355 dated 10-04-2017 Valid legalized Certificate of Licensing and Inspection No. 1701344 dated 10-04-2017
International Availability	United States of America
Decision of RB in 274th meeting	*Registration Board deferred the application for evaluation by Dr. Qurban Ali regarding strain relevance in Pakistan*

The letter for expert opinion was issued on 08-03-2018 and Dr. Qurban Ali has provided the expert opinion on 22-02-2019 as per following details:

Evaluation:

Marek's Disease (MD) is a highly prevalent and important lympho-proliferative disease of chickens. It is controlled in commercial chickens by live virus vaccines consisting of attenuated or naturally avirulent MD-related herpes viruses. Although vaccination programs have been considered effective overall, the poultry industry continues to experience losses due to MD. Given the tendency of MD virus to become more virulent with time (e.g. by reversion to more virulent form) coupled with the economic pressures confronting the poultry industry, there remains a strong incentive to develop safer and more efficacious products that will protect better in the face of early challenge with very virulent field strains without causing adverse side effect.

There are three distinct serotypes of MD virus found in chickens:

1) Serotype 1, the oncogenic form responsible for the disease, including high and low virulence MD virus and their attenuated variants.
2) Serotype 2, a non-oncogenic MD virus; and
3) Serotype 3, herpesvirus of turkeys (HVT)

The early MD vaccines used to consist of serotype 3 virus originally isolated from turkeys. Its lack of oncogenicity, self limiting infection, good replication in vivo and in vitro, availability as cell-free and cell-associated preparations, and high protective efficacy established HVT as a standard for vaccines throughout the world. A commonly used strain of HVT was FC126.

The present product containing (Marek's disease virus, serotype 1, RN1250 strain) is an effective vaccine for Marek's disease, prepared using a recombinant Marek's Disease Virus (MDV), strain CV1988, having been transformed with a foreign DNA construct that includes a long term repeat sequence of a reticuloendotheliosis virus. This safe viral agent elicits a highly protective immune response in chicken against virulent MDV challenge without causing a significant degree of pathogenicity. Suitable formulations of the vaccine for use in chickens include an effective immunization dosage of this novel viral agent, along with pharmaceutically acceptable excipients.

Expert Opinion: This product is recommended for registration.

Decision: Keeping in view the recommendation of veterinary expert, valid legalized Certificate of Licensing and Inspection indicating product availability in country of origin; Registration Board approved the product subject to compliance ofcurrent Import policy for finished drugs.

10. Registration of Imported Human Biological from M/s Morgan Technologies Services, Karachi to M/s Al Habib Pharmaceuticals, Karachi deferred in 262nd meeting.

M/s Al-Habib Pharmaceuticals, Karachi applied for the registration following human biological in their name from M/s Morgan Technologies Services, Karachi. The case was deferred in 262nd meeting as per following details:

Reg. No.& Date	Name of Drug and Composition	Date of application / Fee status	Documentary details	Decision of RB in 262nd meeting
072504 12-8-2011	SCIMAX Injection Recombinant Human Granulocyte	Dy.No. 202 R&I DRAP dated 14-3-	Legalized COPP No. 2014012	*Registration Board deferred*

	Colony-Stimulating Factor Injection Each vial (1ml) contains : Recombinant Human Granulocyte Colony Stimulating Factor (rhG-CSF)…300ug/vial. Shelf life. 02years	2016 Fee deposited Rs.15000/- dated 17-11-2011 + Rs. 35000/- dated 12-4-2013 + Rs.50000/- dated 13-11-2014	dated 25-6-2014 from china. Valid for two years.	*for submission of biosimilarity data and valid legalized CoPP by thefirm.*

The firm then submitted valid legalized CoPP vide no. 2017005 dated 17-01-2017 valid for two years. The firm submitted the biosimilarity data on 17-01-2019 and now the CoPP is not valid. Moreover, the firm submitted that Scimax is a Biotherapeutic product and not a similar biotherapeutic product. It has 174 amino acids while all other branded Filgrastims including Neupogen have 175 amino acids and Scimax is a patent product. The application is for transfer of registration and the product was already registered in Pakistan.

Decision: Registration Board deferred the case for following:

a. **Evaluation report of analytical parameters of the product in light of Pharmacopoeia.**
b. **Tabulated summary of non-clinical and clinical data submitted by the firm.**

11. NobivacDHPPi applied by M/s Vety-Care (Pvt) Ltd. Rawalpindi approved in 271st meeting of Registration Board.

Following veterinary vaccine of M/s Vety-Care (Pvt) Ltd. Rawalpindi was approved in 271st meeting of Registration Board as per following details:

Name of Manufacturer	Brand Name & Composition	Form Dy. No.& Date of Application Price and Pack size	Document details	Decision of RB in 271st meeting
M/s Vety-Care (Pvt) Ltd. Rawalpindi Product License Holder: M/s Intervet Nederland B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands Manufacturer: M/s Intervet International B.V., Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands	NovibacDHPPi Each dose contains: Canine distemper virus, strain Onderstepoort..... ...at least4.0$\log_{10}$ $TCID_{50}$ Canine adenovirus type 2, strain Manhattan LPV3..... at least 4.0 $\log_{10}$ $TCID_{50}$ Canine parvovirus, strain 154..... at least 7.0 $\log_{10}$ $TCID_{50}$ Canine parainfluenza virus, strain Cornell ....at least 5.5 $\log_{10}$ $TCID_{50}$ Shelf Life: 36 months Innovator's Specs	Form-5A Dy. No.3085 (R&I) 13/04/2017 Rs.100,000/- 10-04-2017 Pack Size: 5x1dose 10x1dose 25x1dose 50x1dose Price: Decontrolled	Valid legalized CoPP No. 245962 dated 05-09-2016	Registration Board approved the product as per import policy for finished drugs and as per valid legalized CoPP. The firm will submit Separate application along with fee for diluent.

During processing the case, following points were noted:

i. Typographical error in the brand name of the product: Novibac DHPPias reflected in minutes of meeting while actually it is Nobivac DHPPi as per CoPP & Form 5-A.
ii. The product is freeze dried formulation and diluent is required for its reconstitution

The case was taken up in 276th meeting of Registration Board wherein the Board decided as follows:

"Registration Board decided as follows:

i. Keeping in view the valid legalized CoPP & Form-5A, Registration Board approved the correction in brand name from Novibac DHPPi to Nobivac DHPPi.

ii. Registration Board deferred the application of diluent for clarification whether NobivacDHPPi will be imported in combo pack or diluent will be imported separately."

Now the firm has clarified that the diluent will be imported separately and separate application will be submitted. The firm requested to issue registration letter for freeze dried Nobivac DHPPI.

Decision: Registration Board acceded to the request of the firm for issuance of registration letter for lyophilized vaccine only.

12. Sterile diluent for Vexxitek vaccine deferred in 287th meeting of Registration Board.

Following product of M/s Saadat International, Lahore was approved in 267th meeting of Registration Board as per following details:

Sr. No.	Name of Manufacturer	Brand Name & Composition	Pack Size	Documents submitted	Decision of RB in 274th meeting
1.	Merial, Inc. facilities at 1168 Airport Parkway, SW, Gainesville, Georgia 30501, USA	Sterile Diluent for Vexxitek Each dose contains: Sucrose…0.01025g Potassium Phosphate, monobasic...0.00009g Potassium phosphate dibasic…0.0002g NZ Amine… 0.003g Phenol Red…. ……0.000002g Deionized water… 0.2ml Sodium hydroxide… qs pH Diluent Shelf Life: 36 months	400ml	Valid Legalized Free Sale Certificate dated 26-08-2016 Valid Legalized GMP certificate no. 1603314 dated 22-09-2016	*Approved as per Import Policy for Finished Drugs and as per valid legalized CoPP/ GMP and FSC only for Vaxxitek vaccine.*

During processing the case for issuance of registration letter, the firm submitted that the same diluent will be used for Newxxitek HVT+ND vaccine approved in 271st meeting of Registration Board. The firm has submitted revised Form-5A indicating both vaccines along with valid legalized Certificate of Licensing and Inspection No. 18-01591 dated 29-05-2018 of Newxxitek HVT+ND indicating sterile diluent.

The case was taken up in 287th meeting of Registration Board wherein the Board decided as follows:

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

a. Why the sterile diluent is required separately for Vexxitek and Newxxitek HVT+ND vaccines instead of combo pack."

Now the firm submitted that both vaccines Newxxitek &Vaxxitek are stored/ transported in liquid nitrogen cylinder. However, the diluents is stored/ transported below 30^0C. Therefore,

both the vaccine & the diluents cannot be shipped / stored together. The firm requested to process the cases of vaccine & sterile diluents separately.

Decision: **Registration Board deferred the case for clarification, of import of Vexxitek and Newxxitek HVT+ND vaccines in liquid nitrogen cylinders, by the firm.**

13. Change in manufacturing site of Enbrel 50mg PFS (Reg. No. 062228) applied by M/s Wyeth Pakistan Limited, Karachi.

M/s Wyeth Pakistan Limited, Karachi applied for the change in manufacturing site of their already registered product Enbrel (Reg. No. 062228) as per following details:

Reg. No.	Brand Name & Composition	Previous Manufacturing Site	Newly Applied Manufacturing Site
062228	Enbrel 50mg Pre-filled Syringe Injection Each pre-filled contains: Etanercept……50mg	M/s Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Clondalkin, Dublin 22, Ireland.	Ms Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puur, Belgium.

The firm has submitted the following documents:

a. Application on Form-5A.
b. Fee Challan of Rs. 100000/-
c. Copy of initial registration letter dated 28-04-2010 and corrigendum letter dated 05-11-2010.
d. Copy of approval of change of name of manufacturing site approval dated 03-11-2011.
e. Copy of approval of change of address of importer dated 17-12-2018.
f. Copy of last renewal submission dated 24-03-2015
g. Valid legalized CoPP No. 02/18/122609 dated 30-07-2018 issued by EMA indicating new manufacturing site.
h. Undertaking that the provided information/ documents are true/ correct.

In this context, it is submitted that while processing the case it is observed that as per submitted CoPP, the packaging and batch release site has also been changed from initial registration letter as per following details:

Packaging and Release Site as per Initial Registration Letter	Packaging and Release Site as per newly submitted CoPP
M/s John Wyeth & Brother Ltd. Trading as Wyeth Pharmaceuticals, New Lane, Havant Hampshire, P09 2NG United Kingdom	Ms Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puur, Belgium.

As the firm has submitted the complete fee of Rs. 100000/-, therefore, along with the change of manufacturing site, the above change in packaging and release site may also be approved.

Decision: **Keeping in view the approval of EMA Reference Regulatory Authority); Registration Board approved the change of manufacturing site from M/s Pfizer Ireland Pharmaceuticals, Grange Castle Business Park, Clondalkin, Dublin 22, Ireland to Ms Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puur, Belgium and change of packaging & release site from M/s John Wyeth & Brother Ltd. Trading as Wyeth Pharmaceuticals, New Lane, Havant Hampshire, P09 2NG United Kingdom to Ms Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puur, Belgium as per current Import Policy for finished drugs.**

14. Change of address of importer of already approved product applied by M/s Wyeth Pakistan Limited, Karachi.

M/s Wyeth Pakistan Limited, Karachi submitted that effective August 11, 2017, Wyeth Pakistan Limited deal has been finalized of sale purchase agreement with ICI Pakistan Limited and selling its assets i.e. manufacturing premises holding license no. 000006. Whereas, Wyeth Pakistan Limited will continue operating within Pakistan as an Importer and distributor in future under Drug Sale License/ Wholesale License.

Therefore, the firm applied for the change in address of importer for following already approved product:

Registration Status	Name of Product	Previous Address of Importer	New Address of Importer
Approved in 267th meeting.	Prevenar 13 (Suspension for Injection in Multi-Dose Vial)	M/s Wyeth Pakistan Limited, S-33, Hawkes Bay Road, S.I.T.E., Karachi	M/s Wyeth Pakistan Ltd., B-2, S.I.T.E. Room No. 002 & 003, PGS Amin Block, 1st Floor, Karachi.

The firm has submitted the following documents:

a. Application for change in address of importer.
b. Fee Challan of Rs. 5000/-.
c. NOC for CRF Clearance
d. Site Change approval of SECP
e. Copy of DSL dated 06-07-2018 valid till 21-06-2020

Decision: **Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Wyeth Pakistan Limited, S-33, Hawkes Bay Road, S.I.T.E., Karachi to M/s Wyeth Pakistan Ltd., B-2, S.I.T.E. Room No. 002 & 003, PGS Amin Block, 1st Floor, Karachi for Prevenar 13 Multi-Dose Vial subject to storage facility verification report of new address.**

15. Complain of Brand Name similarity submitted by M/s Hi-Warble Pharmaceutical (Pvt.) Ltd.

Ch. Tariq Ahmed MD M/s Hi-Warble Pharmaceutical (Pvt.) Ltd. in his letter address to Secretary Ministry of NHSR&C on subject "Triplication of Similar Brand Name" has submitted that they got the product Human Immunoglobulinregistered on 9th July 2007 with brand name "Hi-Globin IV" registration No.045723 and came to know through the SRO No.1610(I)/2018, dated 31st Dec 2018 that DRAP has registered a human Albumin with almost similar brand name HL-Globin (only one letter difference) being imported by M/s. Popular International. It has been further stated that these are totally two different drugs, and both are lifesaving but in different indications and his product with registration No.045723 has been registered first (in the market since 2007) and the other product mentioned in SRO No.1610(I)/2018, Sr. No.640, dated 31st Dec 2018, has been registered later on. They have invested a lot of time and expense on this brand to make a reputation and also that was the first brand with this name. Now similar brand name can damage reputation and goodwill of their product. They requested to take immediate action against triplication of brand names to rectify this problem to save the life of the patients by directing the importer i.e.M/s. Popular International to stop its import and sales immediately and also to recall the present stock available in the market.

Importer & Manufacturer	Brand Name& Composition	Reg. No.
M/s Hi-Warble Pharmaceutical (Pvt.) Ltd Lahore Manufacturer: M/s Shanghai Institute of Biological Products, China	HiGlobin I.V. Infusion Each 50ml solution contains: Immunoglobulin IgG…2.5gm Human Albumin….3%	045723
M/s Popular International Manufacturer: M/s Grifols Therapeutics Inc, USA	HL-Globin (PH4) 5% 5vial contains: Human Albumin 5% at PH4	059250

As per condition of registration letter (**The Drugs (Licensing, Registration and Advertising) Rules,1976)**

"The name shall be changed in case it has resemblance with already registered drugs"

The M/s Popular International (Pvt.) Ltd. Karachi has been asked vide letter dated 7-05-2019 to apply for change in brand name because **Hi-Globin** IV" (registration No.045723) of M/s Hi-Warble Pharmaceutical (Pvt.) Ltd. Lahore registered earlier than **HL-Globin** (registration No.059250) of M/s Popular International (Pvt.) Ltd. Karachi. The response of M/s Popular International (Pvt.) Ltd. Karachi is still awaited.

Decision: Registration Board advised DBER to adopt the prescribed procedure for rectification of brand name similarity.

16. Application for change in Brand name of Cosentyx (Reg. No. 088711) applied by M/s Novartis Pharma (Pakistan) Limited, Karachi.

M/s Novartis Pharma (Pakistan) Limited, Karachi applied for the change in brand name of their already registered human biological as per following details:

Reg. No.	Approved Brand Name	Applied Brand Name
088711	Cosentyx	Fraizeron

The firm has submitted following documents:

i. Application with fee challan of Rs. 5000/-
ii. Copy of Initial registration letter dated 24-04-2018
iii. Justification of proposed change
iv. Details (batch number, date of manufacture, quantity and stock position) regarding last batch imported.
v. 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.
vi. Valid Legalized CoPP No. 03/18/122018 dated 09-07-2018 issued by Swissmedic indicating brand name Fraizeron in importing country i.e. Pakistan.
vii. Undertaking that the submitted information is true/ correct.

During processing the case, it was observed that the product license holder of the product has also changed as per following details:

Reg. No.	Brand Name & Composition	Previous Market Authorization Holder	New Market Authorization Holder
088711	Cosentyx Powder for Solution for Injection	M/s Novartis Europharm Limited, Firmley Business Park, Camberley GU16 7SR, United	M/s Novartis Pharma Schweiz AG, 6343 Risch, Switzerland.

	Each vial contains: Secukinumab….150mg	Kingdom.	

The firm was asked for clarification and the firm then submitted the application for change in market authorization holder and submitted the following documents:

a. Application along with fee challan of Rs. 5000/-
b. Copy of initial registration letter dated 24-04-2018
c. Copy of letter of authorization and relationship between Market Authorization holder and manufacturer
d. Revised Sole agency agreement with new market authorization holder.
e. Undertaking that the provided information/ documents are true/ correct to the best of their knowledge.

Initially the registration of the product was granted on the basis of CoPP issued by EMA and now the firm has requested for said changes with the CoPP issued by Swissmedic because as per CoPP issued by EMA the product is not available in country of origin.

Decision: **Keeping in view the approval of Swissmedic (Reference Regulatory Authority); Registration Board approved the change in brand name from Cosentyx to Fraizeron and change in market authorization holder from M/s Novartis Europharm Limited, Firmley Business Park, Camberley GU16 7SR, United Kingdom to M/s Novartis Pharma Schweiz AG,6343Risch, Switzerland.**

17. Procurement of vaccines for Hajj-2019.

A letter from Mr. Muhammad Saleem, Deputy Secretary (HO), Ministry of Religious Affairs & Interfaith Harmony, Government of Pakistan (MoRA&IH), Islamabad having subject "Procurement of Vaccines for Hajj-2019" dated 9th April, 2019 was received. The Ministry had issued a supply order of even number dated 25th March, 2019 to the following vendors being lowest for procurement of vaccines as mentioned against each:

Name of Bidder	Quoted Items	Quantity
M/s Sind Medical Stores, KHI	Meningococcal (Meningitis ACYW-135)	180,000
M/s Sanofi-Aventis, KHI	Trivalent seasonal influenza vaccine	190,000

"The Ministry informed that the above mentioned bidders have submitted that the shelf life of the vaccines mentioned in above said Ministry's supply order may be reduced from 70% to 60%. Furthermore, M/s Sind Medical Stores, Karachi has also revealed that owing to paucity of time Urdu version can't be printed instead to supply in Chinese version. The Ministry requested DRAP to furnish techno-legal comments for supply of above vaccines for the pilgrim's departure to Saudi Arabia for Hajj-2019."

In this context, it is submitted that I&E section of DRAP has already issued a letter No.F.3-4/2014-I&E(pt) dated 19th December, 2014, stating that;

"*The sensitive drugs like vaccines, sera, blood products and other thermolabile drugs having total shelf life of 02 years or less but having remaining / available shelf life 50% or more shall be cleared by the area Assistant Drugs Controller.*

The sensitive drugs like vaccines, sera, blood products and other thermolabile drugs having total shelf life of 3 years or less, but having remaining / available shelf life 60% or more shall be cleared accordingly."

Moreover, for relaxation of Urdu text, the case was referred to Chairman Registration Board. Chairman then advised to confirm whether the firm informed about inability of providing stock with Urdu version during bidding process. The same was confirmed from the copy of letter provided by the firm addressed to Ministry of Religious Affairs & Interfaith Harmony dated 13-02-2019 while the supply order was issued on 25-03-2019.

Further, M/s Sind Medical Stores, Karachi 03-04-2019 informed that they got Purchase order from Ministry of Religious Affairs & Interfaith Harmony, Government of Pakistan (MoRA&IH), Islamabad though letter No.3(5)/2019-pw dated 25th Mar, 2019 for the supply of the following vaccine and quantity for the Hajj-2019:

Sr. No.	Product Name	Pack Size	Quantity	Manufacturer
1.	MENVAC ACYW (Meningococcal Polysaccharide Vaccine – Group ACYW135) 1 Dose Vial (Reg. No.090316)	01 Vial x 0.5ml/1 Dose	180,000 vials	**M/s. Beijing Zhifei Lvzhu Bio Pharmaceutical Co. Ltd.** No.22 Tongji Bei Road, Beijing Economic Technological Development Area, Beijing – CHINA.
2.	Sterile Water For injection 0.5ml Ampoule (Reg. No.090317)	Box of 10 Ampoules x 0.5mL	As per vaccine quantity	**Jiangsu Desano Pharmaceutical Co., Ltd.** No.3, Kangan road, Economic & Technology Development District, Liyang City, Jiangsu Province – CHINA.

"The firm informed that the label of vial / ampoule of the available stocks are in the Chinese language, therefore they are seeking exemption of customized packing for the vial label of the abovementioned vaccine & diluents while the outer packaging and packaging insert will be in customized packing as per prevailing drugs labeling rules. Moreover the firm submitted that they have already informed to MoRA&IH through their letter dated 13-02-2019 (Page/60) about the said situation (Chinese version of vial/ampoule label) and they have no objection to receive the said version stocks due to limited time frame of supply and urgent need of vaccine.

The firm requested that as there is no Meningococcal Polysaccharide vaccine available in the market and due to given timeframe from MoRA&IH (15th April, 2019) for the supply of abovementioned vaccines & quantity, they may be allowed the exemption from customized packing for the vial label of the abovementioned vaccine & diluents while the outer packaging and packaging insert will be in customized packing as per prevailing drugs labeling rules.

Decision: **Registration Board deliberated that reduction of shelf life requirement from 70% to 60% is not the purview of Registration Board. Moreover, as per available record, M/s Sind Medical Stores, Karachi has already informed to Ministry of Religious Affairs & Interfaith Harmony (MoRA&IH) that owing to paucity of time Urdu version can't be printed on the label of vial/ampoule and the supply will be made in Chinese version on vial/ampoule (primary packaging). Yet the supply order was issued to M/s Sind Medical Store, Karachi. Therefore, keeping in view the above fact and urgency of matter due to upcoming Hajj-2019, Registration Board granted the permission of import of meningococcal vaccine with label of vial / ampoule in the Chinese language while the outer packaging and packaging insert will be as per Drugs (Labeling and Packing) Rules, 1986 subject to following conditions:**

i. **This permission shall only be for supply order, of 180000 doses of meningococcal vaccine, issued by Ministry of Religious Affairs & Interfaith Harmony (MoRA&IH)**

for exclusive use in intending pilgrims in Haji camps and not for open market supply.

ii. **Ministry of Religious Affairs & Interfaith Harmony (MoRA&IH) shall maintain the record of quantity of vaccine procured and used against said supply order.**

iii. **In case of pilferages, Ministry of Religious Affairs & Interfaith Harmony (MoRA&IH) shall be responsible.**

18. Request for leaflet update for Cyramza Injection applied by M/s Eli Lilly Pakistan (Private) Limited Karachi.

M/s Eli Lilly Pakistan (Private) Limited Karachi submitted documents regarding leaflet update for products detailed as under;

Sr. No	Reg. No	Brand Name	Pack Size	Requested Change
1.	089814	Cyramza 100mg Injection	10ml vial	• Blood and lymphatic system: Thrombotic microangiopathy • Neoplasms benign. Malignant and unspecified: Hemangioma
2.	091269	Cyramza 500mg Injection	50mL vial	

The firm has submitted following documents;

i. Fee of Rs. 5030/- for each product.
ii. Copy of Registration letters.
iii. Undertaking that proposed label complies all provisions of Drug (Labeling & Packing) Rules 1986.
iv. Copy of Approval letter from Department of Health and Human Services, FDA.
v. Existing leaflet.
vi. New leaflet.

It is submitted that the information has been added in Post marketing Experience under ADVERSE REACIONS.

Moreover, in this context, for such changes, rule position of LRA Rules, 1976, Rule 30(10)(b) states following;

"if a clinical information for a drug is approved by the Drug Regulatory Authority in any of the said countries, the same clinical information shall be considered as approve for drug registration in Pakistan unless modified by Registration Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effect precautions, dosage., etc.

However, the said inclusion has been checked on label/patient package insert available online on FDA website latest of which is of 14-08-2018. It is submitted that in latest label the only inclusion added in Post marketing Experience under ADVERSE REACIONS is '*Thrombotic microangiopathy'*

The firm provided the clarification that receival date of application to Department of Health and Human Services, FDA is 25-10-2018 and last label available on FDA website is 14-08-2018.

Decision: Registration Board deferred the case for following:

a. Updated status of said change on official website of USFDA.
b. Approval status of said change in other reference regulatory authorities.

Item No. V Division of Quality Assurance & Laboratory Testing

Sr.#.	Subject	Status
01	MANUFACTURE & SALE OF SUB-STANDARD PROTONIX 40MG TABLETS, BATCH NO. 052 BY M/S WILSHIRE LABORATORIES (PVT.) LTD., LAHORE.	Personal hearing
02	MANUFACTURE & SALE OF COUNTERFEIT ZOTANIL 3MG TABLETS, BATCH NO.055 MANUFACTURED BY M/S ZANCTOK PHARMACEUTICAL LABS, HYDERABAD.	Personal hearing
03	CASE REFERRED BY PQCB LAHORE REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE PRODUCT SPECIFICATIONS/METHOD OF ANALYSIS.	
04	MANUFACTURING AND SALE OF SUBSTANDARD INJECTION HEPAFERON (INTERFERON) B. NO. 85 BY M/S PHARMEDIC LAB, LAHORE.	Personal hearing
05	DELIGATION OF POWERS TO CHANGE THE PANELS CONSTITUTED BY THE REGISTRATION BOARD. • MANUFACTURE & SALE OF SUB-STANDARD ATROFATE SULPHATE INJECTION, BATCH NO. AT.10118 MANUFACTURED BY M/S BAJWA PHARMACEUTICALS (PVT.) LTD., LAHORE. • MANUFACTURE & SALE OF SUB-STANDARD ANN-VIL INJECTION BATCH NO. H-07616 MANUFACTURED BY M/S VENUS PHARMA, LAHORE.	
06	MANUFACTURE & SALE OF SUB-STANDARD KAWACH GEL BATCH NO. KWI-4116 BY M/S LOMUS PHARMACEUTICALS (PVT) LTD, NEPAL.	
07	MANUFACTURE & SALE OF ADULTERATED & SUB-STANDARD "OXYTOCIN INJECTION (FOR VETONLY)"BATCH NO. 2876 MANUFACTURED BY M/S. ELKO ORGANIZATION PVT, LTD, KARACHI.	

Case No. 01: **Manufacture & Sale of Sub-Standard Protonix 40mg Tablets, Batch No. 052 by M/s Wilshire Laboratories (Pvt.) Ltd., Lahore.**

The FID-VI, DRAP, Karachi visited the premises of M/s Marhaba Medicos, Shop No. 51, Bismillah Market, near New Sabzi Mandi Super Highway, Karachi on 25-04-18 and taken the following sample of drug along with other drugs for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Protonix 40mg Tablet
Composition:	Each tablet contain 40mg Pantoprazole
Registration No:	030041
Batch No:	052
Manufacturing Date:	09-17
Expiry Date:	08-20
Manufactured By:	M/s Wilshire Laboratories (Pvt.) Ltd, Lahore

The FID-VI, DRAP, Karachi has forwarded one sealed portion of sample to Government Analyst, Central Drugs Laboratory, Karachi vide memorandum No.ARS-32-35/2018-FID-VI (K) dated 26-04-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The sealed portion of sample were also sent to Chairman, Registration Board vide letter number ARS-32-35/2018-FID-VI (K) dated 27-04-2018 as required under the provision of clause (b) (3) Schedule V of DRAP Act, 2012.

The sealed sample (manufacturer portion)of under reference drug was sent to M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore vide letter number ARS-32-35/2018-FID-VI (K) dated 30-04-2018 as required under the provision of clause (c) (3) Schedule V of DRAP Act, 2012.

The Federal Government Analyst, CDL, Karachi declared the sample sub-standard quality on the basis of dissolution vide test/analysis report No.R.KQ.310/2018, dated 20th June, 2018 which is violation of section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under. The test report is reproduced as under:

Description:	*Yellow colored, circular shaped enteric coated tablets.*
Identification:	*Pantoprazole Sodium identified.*
Dissolution test:	***Does not comply.***
Uniformity of dosage unit	
By Weight Variation:	*Complies.*
Assay for Pantoprazole Sodium:	
Determined amount/tablet:	*38.2609mg*
Stated amount/tablet:	*40mg*
Percentage:	*95.7%*
Limits:	*90.0% to 110.0% Complies.*

Remarks: *The sample is of **"Substandard"** quality under the Drugs Act, 1976.*

The FID-VI, DRAP, Karachi vide reference No.ARS-32-45/2018-FID-VI (K) dated 26th June, 2018 served an explanation letter to M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore for explaining their position in the manufacturing, selling & distributing of above mentioned substandard drug with direction to recall the above mentioned batch from the market.

In response to the above said explanation letter, M/s Wilshire Laboratories (Pvt.) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore submitted their reply vide letter No. WL/OC/S-221 dated 06th July, 2018 wherein they have stated that they received the sealed portion of their product

Protonix 40mg Tablets (Samples quantity of 30 tablets) while Batch No/Mfg Date/Exp Date was not visible on sample pack. We also receive the sample after 41 days after picking the sample which is violation of Section 19 (3) of the Drugs Act 1976. As guidelines of the Drugs Act 1976 were not followed which is illegal and the said procedure is null and void in the eyes of law. The sample dispatched to us remained in transit during very hot months of May and June while no temperature and humidity conditions were maintained.
Storage conditions are not mentioned on the report where the sample was stored after receipt and we fail to understand as the sample remained untested for 54 days. We had provided reference standard to CDL but we are not sure whether our provided reference standard was used for testing or CDL arranged reference standard from some other source because USP 40 method was used. So, USP reference standard must have been used. Please provide a copy of reference standard of Pantoprazole USP. As per USP method of testing, 68 tablets are required while the sample sent to CDL, Karachi contain 30 tablets so how the required tests can be performed with provided sample.

The FID-VI, DRAP, Karachi was requested to provide the names of responsible persons vide letter No.03-49/2018-QC dated 07th August, 2018. The FID-VI, DRAP, Karachi vide letter No. ARS-32-45/2018-FID-VI (K) dated 09th August, 2018 submitted that updated names of responsible persons may be obtained from Directorate of Licensing Division, DRAP, Islamabad for further processing of the matter.

The Division of Drug Licensing, DRAP Islamabad was requested to provide the names of responsible persons and they provided the following names being responsible persons and technical persons.

M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore	Mr. Ghazanfar Ali Jawa (35202-7157858-5) M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore
Mr. Asad Ali Jawa (35202-2722600-3) M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore	Amjad Ali Jawa (35202-2722635-7) M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore
Ms. Tehseen Tahira (35202-2576262-2) M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore	Mr. Hafiz Nasrullah Khan (33301-1441883-5) M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore
Mr. Muhammad Faisal Javed (31103-1150494-1) M/s Wilshire Laboratories, 124/1, Industrial Estate, Kot Lakhpat, Lahore	

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. 03-49/2018-(QC) dated 06-03-2019.
The firm submitted their reply with reference number WL/OC/S-267 dated 13th March, 2019 which is reproduced as under;
"We recievd letter No. F.ARS-32-35/2018-FID-VI (K) dated 14-05-18 received on 17-05-18 from Mr. Abdul Rsool Sheikh FID Karachi advising us to provide complete specifications/ working standard for our product Protoniz 40 mg Tablet directly to FGA CDL Karachi. This was the first intimation towards us for picking of samples of our products on 25-04-2018 but no sample portion was received by us, neither copy of Form nor place from where he sample was picked.

Being a responsible law abiding company we provided testing methods and working reference standard t FGA CDL vide letter No. WL/B/373-2018 dated 21-05-18.

We received letter No. F.ARS-32-35/2018-FID-VI (K) dated 30-04-18 posted by registered post without stamp received on 04-06-18 along with sealed sam0ple portion of the above said product (Quantity of 30 tablets) while batch No/ mfg date/ Expiry date was not visible on the sample pack. We received sample portion after 41 days which is violation of section 19(3) of the Drugs Act 1976. As guidelines of the Drugs Act 1976 were not followed which is illegal and the said procedure is null and void in the eyes of law.

We had not received any intimation until 17-05-18 and we have not received any copy of sample collection Form till date. The sample dispatched to us remained in transit during very hot months of May and June while no temperature and humidity conditions were maintained.

We received letter No. F. ARS-32-35/2018-FID-VI (K) dated 26-06-18 along with testing report No R.KQ.310/2018 dated 20-06-18 issued by CDL Karachi declaring our product substandard on the basis of non-compliance in dissolution test and it is also mentioned that bill/ warranty produced by M/s horizon Pharma, 108/J, Block-2, PECHS, Karachi is enclosed while it has not been found with the letter. While, no invoice/ warranty was provided with his previous letters as well, so how can we trace and ensure that the product picked by him is manufactured by Wilshire Labs?

We have found CDL test report No R.KQ.310/2018 as vague on the following grounds;

- *Storage conditions are not motioned on the report where the sample was stored after receipt and we fail to understand as the sample remained untested for 54 days.*
- *We had provided reference standard to CDL on 21-05-18 but we are not sure whether our provided reference standard was used for testing or CDL arranged reference standard from some other sourece because as mentioned by CDL, USP-40 method was used so, USP reference standard must have been used. Please provide copy of the primary standard of pentoprazole USP. We are also unaware of the grade and potency with standard solution preparation.*
- *As pr our provided method of testing at least 68 tablets are required for complete analysis while the sample sent to CDL contains 30 tablets so how the required tests can be performed with provided sample?*
- *As per USP-40 method of testing, at least 68 tablets are required (i.e 44 for assays and dissolution and 24 for disintegration and Hardness) while the sample sent to CDL contains 30 tablets so how the required tests can be performed with provided sample?*
- *Our DRAP Registration letter is with "MS Specifications" and same was mentioned on all packaging materials of Protonix 40 mg Tablet, Batch No. 052.*
- *We have provided the method of testing with manufacturers specifications and working standard with Manufacturers Specifications to FGA CDL Karachi vide letter No. WL/B/373 dated 21-05-18 but we are surprised to see that our product was tested as per USP-40.*
- *More over USP monograph requires USP Reference Standard while we had sent working standard with Manufactures Specifications. Reference standard with Manufacturers Specification was used to test the product according to USP-40 which is illegal and against the USP method of testing so the results are null and void.*
- *In Dissolution chapter <711> criterion for acidic stage (A1, A2, A3) and buffer stage (B1, B2, B3) is mentioned while the CDL report is lacking this information too.*
- *As per USP-40, mentioned column is 4.6-mm X 7.5-cm, 3-µm packing L1(C-18). While CDL test report shows column as (C-18) (5 microns with 0.25m-Length and 4.6 n diameter) it proves that wrong column was used for testing of the product.*
- *CDL report shows that column with (C-18) (5 microns) with 0.25m-Length and 4.6n Diameter was used which is astonishing that how a particle with 5 microns can be*

packed in 4.6n Diameter columns. If it exists, please share the source name and copies of invoices so that we are able to procure the same column and own a test to verify results.

- *Injection volume mentioned in USP 40 is 10µl while CDL report shows injection volume as 20 µl which is violation of USP monograph.*
- *Chromatograms for assay and dissolution test are not provided along with CDL Report.*
- *As per USP Monograph, tailing factor and Relative Standard Deviation (RSD) are compulsory while in method provided along with CDL Report lacking this information.*
- *Testing Report No. R.KQ, 310/2018 dated 20-06-2018 declared our product as substandard due to failing in dissolution test. It shows only a phrase regarding dissolution i.e. "does not comply". Please note that dissolution test is a chemical test and for understanding it must be provided with numerical value for each tablet. While, in this report, no detailed/ numeric values are found which shows that dissolution test is performed as per physical observations.*
- *No results for each tablet at acid stager are provided in CDL report. Further, no time and type of medium used, have been mentioned in report/ method.*
- *No, sample preparation and standard preparation and calculations are provided in CDL test method at acid stage.*
- *There is difference between quantitative analysis (mcg) of Sample preparation and working standard preparation. Moreover, no calculations re provided with the reports which confirms that the report as null and void.*
- *No results for each tablet at buffer stage are provided in CDL report. Further, the buffer 6.8 has no clarity for its preparation and salt information is missing whereas USP requires Phosphate buffer to be used.*
- *CDL Report shows assay results as 95.7% and we are surprised that how a product can be declared as substandard in dissolution test while the assay is well within the prescribed limit.*

In light of above mentioned submissions, it is respectfully requested that there are violations of The Drug Act 1976. Moreover, Central Drug Laboratory Report No. R.KQ, 310/2018 dated 20-06-2018 is null and void as numerous legal and technical faults are found in CDL Test Report issued for our product Protonix 40 mg Tablet. So, your letter may please be withdrawn and stop further proceeding. Moreover, as many technical aspects are involved in this case so we request you to please give us a chance for appearing in person for detailed briefing in this regard.

Proceeding of the 289th Meeting of Registration Board.

Hafiz Nasrullah, Senior QCM (11101-1441883-5) and Mr. Shoaib Hakeem, Technical Director (35202-2954794-1) of M/s Wilshire Laboratories (Pvt.) Ltd., Lahore appeared on behalf of M/s Wilshire Laboratories (Pvt.) Ltd., Lahore to plead instant case of Substandard drug Protonix 40mg Tablets, Batch No.052, before the Board in its 289th meeting on 16th May, 2019.

Representatives of the firm re-iterated points already mentioned in their letter as recorded above. After deliberation, firm requested for re-testing of drug product.

Decision: Registration Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided that the Board's portion of the sample shall be retested from appellate laboratory, NIH, Islamabad.

Case No.02: **Manufacture & Sale of Counterfeit Zotanil 3mg Tablets, Batch No.055 Manufactured by M/s Zanctok Pharmaceutical Labs, Hyderabad.**

The FID-V, DRAP Karachi visited the premises of M/s Damam Medical Store, Near Sohrab Goth, Karachi on 16th July, 2018 and taken the following sample of drug along with other drugs for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Zotanil 3mg Tablets
Composition:	Each tablet contain 3mg Bromazepam
Registration No:	058631
Batch No:	055
Manufacturing Date:	04-18
Expiry Date:	03-20
Manufactured By:	M/s Zanctok Pharmaceutical Labs, Hyderabad.

The FID-V, DRAP, Karachi has forwarded one sealed portion of sample to Government Analyst, Central Drugs Laboratory, Karachi vide memorandum No.SAA-45-46/2018-FID-V (K) dated 19-07-18 as required under Section 19(3)(i) of the Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the sample as **Counterfeit** on the basis of **resemblance in the color scheme, text and presentation of outer packaging** with already registered product.

Description: *Pink colored tablets, marked with **"ZPL"** on one side.*

Identification: *Bromazepam identified.*

Disintegration test: *Complies.*

Assay for Bromazepam:

Determined amount/tablet: *3.0723mg*

Stated amount/tablet: *3mg*

Percentage: *102.4%*

Limits: *90.0% to 110.0% Complies.*

Remarks:- *The color scheme, name, text and presentation of outer packaging of the sample **"Zotanil 3mg tablets"** nearly resembles as to be calculated to deceive the label and outer packaging of brand leader drug product **"Lexotanil 3mg tablets"** registration number 001043, manufactured by "Martin Dow Limited Karachi". Hence, sample is declared **"Counterfeit"** under section 3 (f) of the Drugs Act, 1976.*

The FID-V, DRAP, Karachi vide reference No. SAA-45-46/2018-FID-V (K) dated 13-09-18 served an explanation letter to M/s Zanctok Pharmaceutical Labs, Hyderabad that why action may not be taken against them as they have violated the section 3 (f) of the Drugs Act, 1976.

In response to the above said explanation letter, M/s Zanctok Pharmaceutical Labs, Hyderabad submitted their reply vide letter No. Nil dated 27th September, 2018 wherein they have stated that the remarks of the CDL, Karachi should be "The sample is of standard quality with regard to the test performed" instead of the sample is "Counterfeit" under section 3 (f) of the Drugs Act, 1976 which is totally invalid in the eye of law as both the packs are different in respect of (a) front panel, side panel and rear panel (b) text matter (c) product name (well prominent) (d) Company logo (e) Registration number & Manufacturing license and Manufacturer name. They further requested to withdraw the notice as they have not violated the law nor manufactured counterfeit product.

The FID-V, DRAP, Karachi submitted that the firm is involved in contravention/violation of Section 23 (1) (a) (ii) of the Drugs Act, 1976 and recommended that M/s Zanctok Pharmaceutical Labs, Hyderabad may be directed to revise the color scheme of their outer

packaging of their registered product "Zotanil tablets 3mg" in order t avoid confusion in the resemblance in the color scheme and compliance of the section 3 (f) of the drugs Act, 1976.
The FID-V, DRAP, Karachi also provided the names of accused persons as under:

i. M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
ii. Mr. Muhammad Saleem (Partner).
iii. Mr. Wazir Ali Lasi (Partner).
iv. Ms. Shabana Yousuf (Production Manager)
v. Ms. Salma Bibi (QC Incharge)

The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-V, Karachi and they provided the following names being responsible persons and technical persons.

M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	Muhammad Saleem **(Partner)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
Wazir Ali Lasi **(Partner)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	Salma Bibi **(Q.C Incharge)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.
Shabana Sadiq **(Production Incharge)** M/s Zanctok Pharmaceutical Laboratories, SITE, Hyderabad.	

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. 03-71/2018-(QC) dated 26-02-2019.
In response to the show cause notice, the firm submitted that their product complies in respect of appearance, Identification of Bromazepam, Disintegration test, Uniformity of dosage unit by content uniformity and Assay of Bromazepam 102.4% (90 -110%). Therefore, remarks of the CDL, Karachi should be "The sample is of standard quality with regards to the test performed" instead of this the Federal Government Analyst declared the sample Counterfeit, which is totally invalid in the eye of law as both the packs are different in respect of (a) front panel, side panel and rear panel (b) text matter (c) product name (well prominent) (d) Company logo (e) Registration number & Manufacturing license and Manufacturer name. Moreover M/s Martin Dow does not having any objection on the resemblance of lexotanil with zotanil packs.

Proceeding :
The Accused were called for personal hearing before the Registration Board on 16th May, 2019 at 12:00 PM vide letter No. 03-31/2019-(QC) dated 13th May, 2019 but no one appeared before the Board.

Decision: Registration Board decided to give second opportunity of personal hearing to the accused in the next meeting and deferred the case".

Case No.03: CASE REFERRED BY PQCB LAHORE REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE PRODUCT SPECIFICATIONS/METHOD OF ANALYSIS.

The Secretary, PQCB, Punjab vide letter no. PQCB/Dtl-D/197/2018 dated 20-12-2018 addressed to the Chief Executive Director Officer, DRAP, Islamabad with request to look into the matter personally and to direct the quarter concerned to expedite the matter.

Brief Facts of the Case:

The Director, Drug Testing Laboratory, Rawalpindi, Lahore and Bahawalpur reported that they have to file the cases pertaining to testing of the various drug samples due to non co-operation of the manufacturers. These firms failed to provide method and standards for test/analysis due to which it was not possible to conduct test/analysis and to report the same in the best public interest. The Directors DTLs have requested the Board to recommend the DRAP for cancellation of registration of the following Drugs whose test/analysis method/specification were not provided to the Government Analyst concerned by the pharmaceutical firm, as according to the clause XIX of the condition of registration of the drugs under the section 7 of the Drugs Act, 1976, manufacturer is bound to provide the complete method of analysis of the product.

S/N	DTL	Drug Inspector Area	Form 6 Date	DTL letter No. and Date	Manufacturer	Product name	Reg.No	Reason
1	Rawalpindi	Deputy Drug controller Hassan Abdal	11-10-2018	LR/DS/2018/561 17-11-2018	M/s Lisko Pakistan pvt Ltd	Tablet Muscadol Forte Batch No.061	067174	No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTl dated 18-10-18, 30-10-18 & 06-11-18
2	Lahore	DI Aziz Bhatti town Lahore	03-09-2018	6032/DTL 7-11-2018	M/s Ferroza international Pharma Lahore	Tab. Melide (Nimsulide 100mg) Batch No. 019	035543	No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTL dated; 12-09-18, 28-09-18 & 11-10-18.
3	Bahawalpur	DI Tehsil Okara	12-10-18	2002 15-11-2018	M/s Danas Pharma (Pvt) Ltd	Cyclofen Batch No.TA945	054592	No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTl dated; 17-10-18, 29-10-18 & 06-11-18

The case was considered by the Provincial Quality Control Board, (PQCB) Punjab in its 196th meeting held on 13-11-2018. The Secretary, PQCB appraised the Board about the background of the case which was discussed at length. The Board observed that all the manufacturers/ drug Registration certificate holders are legally bound to provide product specifications and method of analysis to Government analyst/Drug testing Laboratories as and when required. The need for product specification/method of analysis becomes more critical when the drug is not available in the official pharmacopoeia and/ or the manufacturer has its own customized speciation/ method

for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample without having manufacturer specification/method of test/analysis.

The Board expressed its serious concerns over casual behavior and non co-operation on the part of the above listed firms in this regard. The Board after detailed discussion and deliberation decided to allow the provincial Drug Testing laboratory, Multan to file only those cases where Manufacturer Specifications are not provided by the respective firm and also not available in official compendia. Furthermore, the Board decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drugs listed above, in best public interest.

Proceeding and Decision:

The case was presented before the Registration Board in its 289th meeting on 16th May, 2019 and the Board after detailed deliberation and decided to issue the show cause notice for suspension / cancellation of drugs to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for not providing the specifications/method of analysis of the above said products manufactured by the said manufacturers to the Drug Testing Laboratories."

Case no.4: Manufacturing and sale of substandard injection Hepaferon (Interferon) B. no. 85 by M/s Pharmedic lab, Lahore.

The brief of the case for consideration of the Registration Board
Background of the case.

The background of the case is that the Registration Board in its 248th meeting held on 18th-19th March, 2015 discussed the case of supply of sub-standard Hepaferon Injection (Interferon) to Government of Khyber Pakhtunkhwa Batch No.80-87. The Federal Inspector of Drugs (FID) Peshawar was directed by the Registration Board to submit the certified copies of decisions of Drug Court Peshawar and Peshawar High Court, Peshawar in the instant case. The FID has submitted the copies of the orders the Peshawar High Court, Peshawar and the copies of decision of Drug Court Khyber Pakhtunkhwa, Peshawar The Board after thorough deliberations and in the light of decisions of the Courts and view point of the member from the M/o Law Justice and Human Rights decided the case as under:-

"Registration Board was briefed about the background of the case. Sheikh Sarfraz Ahmad, representative from Ministry of Law was of the view that after the decision of the Drug Court Peshawar a fresh reference requires to be sent to Law Division for seeking opinion. The Board agreed to the proposal".

Decision:

The Drugs Registration Board decided that the opinion of Law Division may be solicited in the light of decision of the Drug Court, Khyber Pakhtunkhwa, and Peshawar which are self explanatory in which the Honorable Drug Court ordered that the complaint of the prosecution is dismissed.

Decision of the 254th Meeting of the Registration Board.

Report was being prepared both by the Federal Inspector of Drugs and Provincial Drug Inspector for submission the Honorable Court. When the investigation was under process by FID and Provincial Drug Inspector completed his investigation is submitted before the Court on the basis of report submitted by Provincial Drug Inspector the court acquitted the accused Later when the report of FID was completed, the time for filing appeal had also lapsed.

In this case Federal Drug Inspector should have intervened through Peshawar High Court for stopping the drug court from announcing its decision till the time the report of Federal Inspector of Drug was completed this was must done.

Presently the accused stand acquainted and Board cannot ensure notice to the accused on the here of report of FID because the accused stand accqumtted by the Court

The Law division has decided to consult additional Attorney General DAG for filling application before the court for already condonation of delay in order to file an appeal.

The Board has decided to consult the DAG through Legal Affairs Division of DRAP for filing application on condo nation of delay The decision was communicated to Deputy Director Legal Affairs on 22nd August 2016.

The Federal Inspector of Drugs (FID) Peshawar was directed by the Registration Board to submit the certified copies of decisions of Drug Court Peshawar and Peshawar High Court, Peshawar in the instant case. The FID has submitted the copies of the orders the Peshawar High Court, Peshawar and the copies of decision of Drug Court Khyber Pakhtunkhwa, Peshawar The Board after thorough deliberations and in the light of decisions of the Courts and view point of the member from the M/o Law Justice and Human Rights decided the case as under:-

*"Registration Board was briefed about the background of the case. Sheikh Sarfraz Ahmad, representative from Ministry of Law was of the view that after the decision of the Drug Court Peshawar a fresh reference requires to be sent to Law Division for seeking opinion. The Board agreed to the proposal"***.**

The Drugs Registration Board decided that the opinion of Law Division may be solicited in the light of decision of the Drug Court, Khyber Pakhtunkhwa, and Peshawar which are self explanatory in which the Honorable Drug Court ordered that the complaint of the prosecution is dismissed.

Keeping in view of the decision of the Drug Court Khyber Pakhtunkhwa, Peshawar the M/o Law Justice and Human Rights is requested to furnish view/ comments as whether the responsibility fixed by Federal Inspector of Drugs, Peshawar under Section 23(1)(a)(v)(vii) and 23(1)(a)(vii), 23(1)(b)(f) of Drugs Act, 1976 for prosecution **(Annex-IV)** may be set aside after the decision of the Drug Court Khyber Pakhtunkhwa, Peshawar or otherwise.

As per reference para 433/N FID Peshawar informed that he sent 02 letters to DAG office Peshawar on 05th August and 25th August 2016 but no reply receive from DAG office Peshawar then on 30th August 2016. The FID mentioned that he personally went to DAG office Peshawar High court Peshawar Mr. Manzoor Khan Khalil Senior DAG Peshawar High Court. The DAG informed the FID Peshawar that they cannot give any opinion/comments on the case relevant case.

The FID Peshawar further informed that the DAG also directed him to submit an application to Law Division Islamabad for legal opinion and when Law Division Islamabad shall refer the subject case to DAG office Peshawar High Court then they will look into the subject matter and give legal opinion/comments.

The Federal Inspector of Drug Peshawar forwarded the FR to Director QA, DRAP Islamabad wherein the FID submitted the details of the instant case which are as under:
The case of Hepaferon (Interferon) manufactured by Pharmadic Lahore has been devided into three phases/parts as under:-

1. **Part/phase 1.**

On 01/04/2013 on the Telephonic direction of DDC (QC) (QA) the FID visited Chief Drugs Inspector Khyber Pakhtunkhwa Mr. Sabir Ali to get initial information about the case which was communicated to DRAP Islamabad on 26.04.2014 vide letter No.F.3-20/2013-FID-DRAP-119 after getting the initial and unsigned substandard report from provincial govt. the FID issued a letter to Chief Executive Pharmedic Lab. Lahore and asked to provide the following information vide this officer letter No.F.3-20/2013-FID-DRAP 868 dated 08-04-2013 and reminder and in reference to telephonic direction from Director Biological directed the FID to get the status and storage condition of the Hepaferon lying in LRH Car parking premises the detailed report submitted to Director Biological DRAP Islamabad vide this office letter No. F.3-20/2013-FID-DRAP-1288 dated 25-04-2013 desiring detailed information about the case the FID and in reference to Director Biological Drugs letter No.F-1/-4/2013 dated 25-04-2013 desiring detailed information about the case the FID submitted a detailed report about the preceding of sampling by provincial drugs inspector and report submitted by Director DTL and by anticorruption from unknown Laboratory submitted to Director Biological vide this office letter No. F.3-20/2013-FID DRAP-1288 dated 08-05-2013. Under direction of Chief Justice High Court Peshawar the Director General Health Services requested DRAP Islamabad to conduct sampling from the stock of Interferon lying in the premises of LRH Peshawar. The Director General Health Services issued a letter on 02-08-2013 vide office letter No. S.O (Drugs)/H/2-43/2013-Re-examination to Director Federal Govt. Analyst National Control Laboratory for Biological Islamabad and in response DG Health Services KPK letter the DRAP Islamabad issued a letter to the FID to take sample of Hepaferon Inj. Mfg and supplied by Pharmadic Lahore from LRH and from the stores the stock lying in the company M/s Pharmadic Lahore premises vide letter No. F.3-15/2013-QC dated 19th August 2013.

The FID vide DRAP Islamabad letter No. F.3-15/2013-QC dated 31-005-2013 coordination with Director General Health office and Director Anticorruption office to send their representative as witness during sampling on 15-08-2013 and reminder issued on 24-06-2013 vide this office letter No.F.3-20/2013-FID-DRAP-1674. The FID along with representative of DG Health and Director Anti Corruption office drawn samples from three containers on Form-3 on 15-08-2013 from the stock of Interferon (Hepaferon) Injections of the available batches of Batch No. 80,82,85 and 87 lying at different temperature of 4.7 C 35 and 38 C and sent to govt. Analyst Biological NCLB on Form 4 dated 15-08-2013 summary of storage condition and samples submitted to Director Biological National Laboratory Islamabad vide this office letter No.F.No.3-20/2013-FID-DRAP dated 15-08-2013. Sampling received by Director Biological Islamabad on16-08-2013 copies of Form3 and Form-4 and detail report of storage condition submitted to Director Biological and DG Health Services KPK and DDC (QC) Islamabad for Information.

On 27-08-2013 vide this office letter No. F.3-20/2013-FID-DCA (P)2134 a detail report about sampling and storage condition submitted to Director General Health Services for information
On 26-08-2013 manufacture portion sent to Manager (QC) M/s Pharmadic Lab Lahore

On 22-10-2013 the office receive all the test report of Interferon from NCLB from B.No.80-87 stock lying in three containers at the basement car parking of LRH hospital Peshawar which are as under :-

S.No.	Name of Drug	B.No. and Temperature	Test Report No. & date	Results/Remarks
01.	Hepaferon Injection 3 MIU (Interferon Alpha 2a)	80(+38 C)	FS-2013/17 14-10-2013	Substandard
02.	do	81(4.7 C)	FS-2013/13 14-10-2013	Substandard
03.	do	82(+38 C)	FS-2013/13 14-10-2013	Substandard
04.	do	82(4.7 C)	FS-2013/13 14-10-2013	Substandard
05.	do	83(+38 C)	FS-2013/13 14-10-2013	Substandard
06.	do	83(4.7 C)	FS-2013/13 14-10-2013	Substandard
07.	do	84(4.7 C)	FS-2013/13 14-10-2013	Substandard
08.	do	85(35C)	FS-2013/13 14-10-2013	Substandard
09.	do	87(+38 C)	FS-2013/13 14-10-2013	Substandard

On 22-10-2014 copies of attested tests reports were submitted to DG Health KPK Peshawar Chief Executive officer DRAP Islamabad Director Anti Corruption Peshawar and Director Pharmadic Lab Lahore with direction to stop sale and recall all the stock from the market.

On 30-10-2013 after receiving the substandard tests reports of Hepaferon (Interferon) from batch No.81-87 the FID visited the storage area of Hepaferon at LRH Car Parking and took the details of stock by physical checking/counting batch wise quantity manufacturing and expiry date recorded on Form-I and ordered under section 18(1) of the Drugs Act 1976 requiring a person not to dispose of stock in his position and sign taken from the store keeper of cold chain system kept in three container at LRH under safe custody of Rehmatullah Khan Sahibzada Khan Barkat Ali Cold Chain operators and Mr. Mohammad Ibrahim Cold Chain supervisor Signature taken on Form-I from all the responsible persons mentioned above.

In reference to the substandard report show cause issued to Chief Exeutive M/s Pharmadic Lahore vide this office letter No.F.10-77-85/2013-LRH-DRAP-2651 dated 28-10-2013 and directed the firm to recall the stock of the said drug from the market and from your distributer outlets under intimation to this office and also directed to provide the sale record batch History and names of Directors and technical staff in QA and production with NIC No.

Another letter No.F.10-77-85/201-LRH-DRAP 2951 dated 29th November 2013 issued to DG Health Services KPK Peshawar with direction not to use these substandard drugs Hepaferon (Injection) B.No.80-87 kept in three container at LRH car parking and inform the same to all field DHQs offices and Health centers not to use the same batch no. whereas available.

On 12.3.2014 a letter issued to Chief Executive M/s Pharmadic Lahore to provide the name of Director/Chief Executive with NIC copy Name of Production Incharge Name of QC Incharge

valid copy of DML issued by DRAP Islamabad The same letter was sent to DDG (E&M) Lahore vide this office letter of even No. dated 12-03-2014 with request to ensure the compliance of this letter through your area FID

The reply of the firm was received vide their letter No. Ref.No.PH/LHR/18225 dated 28-03-204 in which they have provided all the required information name of director/chief executive name of production Incharge QC Incharge along with copies of CNIC and valid copy of DML

Another reply of the firm was communicated to this office by area FID Lahore on 25-112013 vide firm letter No.RefPh/LRH/18062 dated November 02, 2013 in which the firm blames the Director Health for not maintaining the temperature of the cold storage rooms of the 3 containers lying at LRH car Parking but did not provide the undertaking about the storage condition between the firm and DG Health Services KPK who was responsible to maintain the storage condition 2-8 C

In light of above mentioned storage condition and substandard test report received form govt. analyst NCL Biological Islamabad the firm has violated section 23 of Drugs Act 1976 therefore the Director Itikhar Ahmad Sheikh CNIC No.35202-0328994-9 production Incharge Mazhar Hussainan Quality control Incharge Mr. Asim Mehmood of the firm as mentioned above may please be prosecuted in Drugs Court alongwith Director program Hepatitis KPK Dr. Ghulam Subhani store keeper Mr. Mubarak shah may please be nominated as co accused in the case due to negligence or intentionally the storage condition was not maintained from 2-8 C nor tested after purchase and gave huge loss to public money The FID ordered to stop the use of hepaferon on Form-I under section 18(1) of Drugs Act 1976 due to particle and not maintaining the storage condition of the 3 containers lying/kept in the premises of LRH Hospital by KPK Govt.

Part 2.

On the other hand interferon Injection Batch Nos. 87 and 88 sampling conducted from DHQ Hospital Mardan on 23-12-2013 on Form-3 and samples sent to the Director National Biological Islamabad on 24-12-2013 and test reports received from National Institute Biological Islamabad with standard Quality vide Test report No.FS2013/31 and 32 dated 22-02-2014 with the remarks The sample is of standard quality with regards to tests performed however being a biological product this sample report is not applicable to whole lot or some other portion of the same lot stored elsewhere under different storage conditions which needs clarification by the govt analyst NCL Biological because when any sample is drawn from any stock/premises in random it covers the whole stock but the remarks of govt. analyst is doubtful needs clarifications The same repot communicated to DDC (QC) DRAP Islamabad and copy to DG Health KPK and Director M/s Pharmadic Lahore on 20-03-2014 and letter issued to Director NCL for Biological/Govt. Analyst for clarification Reply is still awaited.

During sampling of Hepaferon Injection (Interferon Alpha 2A 3MIU/ml batch No. 87 and 88 storage condition was found maintained between 2-8C.

However on further scrutiny of the record of DHQ Mardan following fact were revealed

1. The hospital was supplied 180.000 vial of Hepaferon vials in 2011 as per receipt No. Nil dated 22-04-2011. The receipt did not indicate any batch No..
2. However as per statement of store keeper MS DHQ Mardan the stock was returned to M/s Pharmadic for keeping in their cold storage facilities on behalf of hospital then the hospital make arrangement for its own appropriate storage facilities.

3. An undertaking by M/s Pharmadic Lab Dated 22-04-2014 was also found in the record to that effect that the firm will supply the balanced interferon as and when required by DHQ Mardan
4. A receipt dated 26-05-2012 issued by M/s Pharmadic indicate the 180,000 vials interferon was received by M/s Pharmadic Lab Lahore
5. A delivery Challan D.C No.3 dated 26-02-2011 issued by M/s Pharmadic indicate that DHQ Mardan was supplying 180,000 Hepaferon Injection Batch No.87 and 88
6. Lot release certificate of Batch No. 87 and 88 is enclosed

In view of above documents/ statement obtained from record of DHQ Hospital Mardan there appeared to be a number of Locumas which create doubts on the whole process of receipt and return of stock by DHQ Mardan.

Some documents received from the store Keeper given to Anti Corruption during investigation copies stock of 180,000 vials on dated 26th May 2012 and another letter of undertaking issued by pharmedic on 22-04-2011 regarding 180,000 vials letter received by the office of the Medical superintendent DHQ Hospital Mardan by Aurangzeb store Incharge dated 22-04-2011

Statement of MS Dr. Nigar Ahmed DHQ Hospital Mardan dated 03-06-2013 given to Anti Corruption Circle Peshawar In which he states that store Keeper informed him about the arrival of Hepaferon and with the directive of Director Hepatitis on telephone we received the stock and on the direction of Project Director Hepatitis as per the statement of store keeper Mr. Aurangzeb the stock was received and retuned back to M/s Pharmadic Lahore for keeping at their cold storage until the DHQ Mardan will not arrange their own cold storage facilities as per stamen of store keeper Mr. Aurangzaib DHQ Mardan

Part 3

On the request of Director Hepatitis Program KPK and the DRAP Islamabad issued direction to Fid Lahore to take samples from the stock of KPK Government lying with M/s Pharmedic Lahore custody quantity is 837894 vide letter No.4186/PHCP dated 13-01-2014

In continuation to DRAP letter direction Mr. Ajmal sohail area FID Lahore and Dr. Akbar Ali area ADC Lahore visited the premises of M/s Pharmedic Lahore an checked the stock of Hepaferon of the stock of KPK government and it was observed that all the stock of interferon of B.No. 81, 82, 88, 89, 90, 91, 92, 93, 94 and 95 was found kept at room temperature. Therefore the panel could not take samples for test analysis as the storage condition was not maintained under section 18(I) of the Drug Act 1976 requiring a person not to dispose of the stock in his possession on Form-I and required the concerned authority to grant permission for extension in not to dispose of period under clause (i) of subsection (I) of the section 18 of the Drug Act 1976 for 3 months or till the decision

The FID submitted that they are also sending complete suo Moto judgment copies of Honorable High Court Peshawar for information and necessary action attached with this letter

Keeping in view all the facts and correspondence and substandard tests reports issued by Govt. analyst NCL Biological Islamabad the following persons may please be included in prosecution under section 23(1)(a)(v)(vii) and 23(1)(a)(vii) and 23 (1) (b) (f) violation of cold chain storage condition who are directly or indirectly involved

Accused

i. Mr. Iftikhar Ahmed Shiekh, Director/C.E.O
ii. Mr. MazharHussain, Production Incharge.
iii. Mr. AsimMehmood, Quality Control Inchage

Co Accused

i. Dr. GhulamSubhani Director Hapatitis Program (Co-accused)
ii. Mubarik Shah, Store Keeper LRH Hapatitis Program (Co-accused)
iii. Dr. Nigar Ahmed, Ms DHQ Mardan
iv. Mr. Aurengzaib, Store Incharge, DHQ Mardan (Co-accused)
v. Dr. Chuhan Director (Co-accused),
vi. Dr. Sharif, Director (Co-accused)

Witness

1. Mr. Abdul Samad Khan Director/ Federal Govt.analyst NCL for Biological Islamabad.
2. Mr. Rehmatullah Baig Alvi, FID, Peshawar.
3. Mr. Adnan Shaidullah ADC Peshawar.
4. Mr. Ajmal Sohail Asif area FID Lahore.
5. Dr. Akbar Ali area ADC Lahore.
6. Dr. Haroon Director Hepatitis Programme, KPK.
7. Mr. Khawaja Mohammad Kahn sub inspector then anti corruption Peshawar.
8. Mr. Zahid Ali Khan Pharmacist Government KPK MCC Director office.
9. Mr. Zakir Drugs Inspector Peshawar.
10. Mr. Tayyab Abbas Drugs Inspector Peshawar.

Proceeding and decision of 279th meeting of DRB:

The Board decided to issue the show cause notice and personal hearing to the accused persons of the firm responsible for manufacturing and selling of substandard interferon injection, as the purchaser had purchased the injection under the warranty issued by the manufacturer. Hence, they are protected under section 32 of The Drugs Act, 1976.

Proceeding and decision of 284th meeting of DRB:

The board deferred the case till the next meeting of Registration Board.

Proceeding and Decision of the 286th Meeting of Registration Board.

Mr. Syed Anees Ur Rehman Kirmani (Manager Regulatory Affairs) of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore and Shahid, Advocate (35200-1420583-9) appeared on behalf of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore to plead instant case of Substandard Hepaferon Injection (Interferon) drug before the Board in its 286th meeting on 16th November, 2018. The Board decided to defer the case keeping in view of the request of the firm for detailed show cause notice to the accused persons and to come up in the upcoming meeting of Registration Board."

Show cause notice was served to the firm and accused as per decision of 286th meeting of the Registration Board dated 09th April, 2019 and their reply is still awaited.

Proceeding and decision:

Mr. Syed Anees, Regulatory Manager(38403-868689026-9) of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore and Shahid Sulehri, Legal Manager (35200-1420583-9) appeared on behalf of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore to plead instant case of Substandard Hepaferon Injection (Interferon) drug before the Board in its 289th meeting on 16th May, 2019.

The representative of the firm informed the Board that delay in reply to show cause notice was due to unavailability of the Chief Executive Officer of the firm, as he was abroad. They also submitted written reply to the show cause notice issued to them vide reference No.03-48/2013- (QC) dated 09th April, 2019.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided to thoroughly review the reply of the show cause notice and defer the case till next meeting of the Registration Board.

Case No. 05: Deligation of Powers to Change The Panels Constituted By The Registration Board.

Sometime the inspection of any facility could not be conducted due to non availability of the any of the members which delays the inspection. Sometimes the inspections are delayed for long period. It is therefore proposed that to avoid unnecessary delays, the powers to constitute or reconstitute the panels may be delegated to the Director, QA&LT, DRAP, Islamabad so that unnecessary delay me be overcome.

01. Manufacture & Sale of Sub-Standard Atrofate Sulphate Injection, Batch No. AT.10118 Manufactured By M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore.

FID-II, DRAP, Lahore visited the premises of M/s Bajwa Pharmaceuticals Industries, 36-km GT Road, Gujranwala Road, District Sheikhupura on 21-02-2018 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:	Atrofate Sulphate Injection
composition	Each ml contain 1mg of Atropine Sulphate
Registration No:	085776
Batch No:	AT.10118
Manufacturing Date:	Jan.2018
Expiry Date:	Dec.2019
Manufactured By:	M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore

FID-II, DRAP, Lahore has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.2999/2018-DRAP (L-II) dated 01-03-2018 as required under Section 19(3) (i) of the Drugs Act, 1976.

FID-II, DRAP, Lahore has also forwarded one sealed portion of sample as Board's Portion vide letter No.3000/2018-DRAP (L-II), dated 01-03-2018 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 vide test/analysis **report No.LHR.26/2018**, on the basis of pH (**pH determined= 5.72, Limits= 2.8-4.5**) dated 20th April, 2018.

FID-II, DRAP, Lahore vide letter No.5464/2018-DRAP (L-II) dated 24-04-2018 directed M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore to recall the said drug on war foot basis.

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore submitted their reply vide letter No.BPL/MOH/18/101dated 14-05-2018 wherein they challenged the results of the CDL, Karachi and requested for retesting of sample by appellate laboratory – NIH, Islamabad U/S 22 (4) of the Drugs Act, 1976.

On the request of the firm, sample was sent for the appellate testing from Appellate laboratory, NIH, Islamabad dated 13-08-2018 under section 22(5) of the Drugs Act, 1976 after seeking due approval from the Chairman, Registration Board (in exercise of delegated power of Registration Board in it 283rd Meeting held on 27 to 29th June, 2018) as required U/S 22(5) of the Drugs Act, 1976.

The Appellate Laboratory – NIH, Islamabad vide their test report No.018-M/2018 dated 04-10-2018, has also declared the sample as of **Sub-standard** quality on the basis of pH **(pH determined=6.08, Limits= 2.8-4.5)**.

Stance of The Firm:

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore vide reference No.BPL/MOH/18/138 dated 03 November, 2018 have stated that upon testing of samples in quality control lab, pH of Atrofate sulphate (Atropine sulphate 1mg/ml) injection was found within limits as per BP 2017 specifications.

They stated that all other tests complied BP specs such as assay, physical Appearance, BET and sterility but pH showed compliance with USP 39 specifications instead of BP specifications. However pH results did not interfered physical appearance and no complaint was received from health section regarding pH doing harm for human.

They further requested that production of the said product is stopped on the orders of FID and if they are given a chance to resume production of the said injection, it would be very helpful to overcome the shortage of emergency product in major hospitals. They further requested to review their product as they are under immense pressure from major institutional hospitals.

Remarks of the Deputy Director (Quality Control):

The sample of Atropine Sulphate was declared on the basis of Ph limits. The company stopped production of the said product and conducted investigation. They also conducted the stability studies. Furthermore the said product is reportedly short item. The case is yet to be considered by the Registration Board. To save the time it is proposed that a panel may be constituted for verification of the stability data and product specific inspection, so that if the company fulfills the criteria, they may start production to avoid market shortage and to ensure free availability.

Proceeding and Decision of the 287th Meeting of Registration Board.

The facts of the case were presented before the Registration Board in its 287th meeting on 04th January, 2019. The Board deliberated the matter in depth in the light of available record/ remarks of the Deputy Director (Quality Control), decided as under:

I. Verification of the stability data provided by the firm as soon possible by the following panel of inspectors:
   - Additional Director, DRAP, Lahore.
   - Dr. Shafiq Ur Rehman, Director, DTL, Lahore.

The above said decision was communicated to the firm and panel members vide letter No.F.03-92/2018-QC (287-RB) dated 28th February, 2019.

M/s Bajwa Pharmaceuticals (Pvt.) Ltd., Lahore vide reference No.BPL/MOH/19/159 dated 29th April, 2019 stated that since the issuance of above said letter, the firm has still not been inspected by constituted panel of inspectors. They further requested to reconstitute the panel to resolve the matter and oblige.

Proceeding and decision of the Board.

The case was presented before the Registration Board in its 289th meeting on 16th May, 2019 for reconstitution of the panel which was constituted by the Board in its 287th meeting and the Board reconstituted the panel as follows;

a) Director, Drug Testing Laboratory, Lahore.
b) Area Federal Inspector of Drugs.

02. Manufacture & Sale of Sub-Standard Ann-vil Injection Batch No. H-07616 manufactured by M/s Venus Pharma, Lahore.

The sample of Ann-vil Injection Batch No. H-07616, Reg. No.012083, manufactured by M/s.Venus Pharma, Lahore has been declared **Sub-Standard** by Federal Government Analyst vide test report No. LHR.292/2016, dated 21st June, 2016. The sample of failed drug was taken by FID Faisalabad at Lahore, on 12-04-2016 from Manufacturer's Premises for test/analysis. The results of CDL, Karachi on the basis of which the subject stated product was declared substandard are as under;

Substandard with regard to;

Bacterial Sterility Test: (With protocols of test applied) Manufacturer's specifications Does not comply.

Procedure: Put the content (gauze) of the sample in presterilized thioghycollate medium, kept in medium flask. Incubate the same medium flask at 30˚C to 35˚C for 14 days.

Acceptance Criterion: No growth of micro organism occurs.

On explanation letter issued by the FID Faisalabad at Lahore on 20-07-2016, M/s Venus Pharma, Lahore submitted a reply vide its letter No./VP/FY/49/16, dated 23-07-2016, wherein the firm challenged the test/analysis report of CDL Karachi for retest by Appellate Laboratory at NIH, Islamabad. The Appellate Laboratory also declared the sample Substandard vide test report No. 020-M/2016 dated 20th October, 2016. The results of Appellate Lab, NIH, Islamabad on the basis of which the subject stated product was declared substandard are as under;

(With protocols of test applied) Manufacturer's specifications

Description: Colorless liquid contained in amber colored labeled glass ampoules having fibers and particles packed in an outer carton. **(Does not comply with manufacturer's specifications which states that Ann-vil Injection is clear colourless solution).**

In the light of Appellate Laboratory test report, the FID served an explanation letter dated 09-12-2016 to the firm. In its reply vide No. / VP/FY/49/16 dated 13-12-2016, the firm M/s Venus Pharma Lahore has pleaded that the report of NIH is incomplete on the following grounds:-

i. NIH has not mentioned the method of inspection of fiber and particles.
ii. It has not been clarified that how the visual inspection was carried out i.e., by naked eye or by some equipment.
iii. NIH has not pointed out the nature and size of particle.

FID Faisalabad at Lahore furnished the names of responsible persons as under;

i. Mr. Pervaiz Iqbal Siddique, Managing Partner.
ii. Mr. Akbar Ali Malhi, Production Manager.
iii. Miss Saadia Khan, Quality Control Manager
iv. Mr. Muhammad Usman Akhtar, Quality Assurance Manager

In response to show cause notice issued to the firm on 09th March, 2017, the firm M/s Venus Pharma, Lahore submitted its reply to show cause notice dated 15-03-2017. The firm stated that according to CDL test report No. LHR.292/2016 the sample was cleared in all tests i.e. Visual Inspection, pH, Volume, Identification and Assay except Sterility test. The result was challenged for retesting from NIH Islamabad and according to test report No. 020-M/2016, the product is clear in all tests including the sterility test. However NIH has pointed out the fiber and particle in the sample. The firm further stated that the report of NIH is incomplete because the NIH Analyst

has failed to mention the method of inspection of fiber and particles. It has not been clarified that how the visual inspection was carried out i.e., by naked eye or by some equipment. Moreover NIH has not pointed out the nature and size of particle because as per Honorable High Courts of KPK, Punjab and Sindh, the test report is invalid until and unless the Nature and Size of particle is not indicated. Moreover, neither the FID nor CDL had seen the Fibers / Particles.
The accused persons of the firm, M/s Venus Pharma, Lahore were called for personal hearing.

Proceedings:

The subject case was considered by the Registration Board in its 270th meeting dated 26-05-2017. Mr. Umair Pervaiz, Director and Mr. Hafiz Nisar Ahmad, Production Manager of the firm M/s Venus Pharma, Lahore appeared before the Board and pleaded their case. Umair Pervaiz, Director, M/s Venus Pharma, Lahore argued that the Appellate Lab Lahore declared the product substandard on the basis of description having fiber and particle but they tested/analyzed their retention samples and the recalled samples which are clear. On inquiry raised by Secretary Registration Board, Dr. Obaidullah, Director, M/s Venus Pharma, Lahore told that they use USP type I ampoules for their product.

Decision:

The Registration Board after detailed discussion, deliberation, considering all the pros and cons of the case and discussion with Umair Pervaiz, Director and Mr. Hafiz Nisar Ahmad, Production Manager of the firm M/s Venus Pharma, Lahore, decided the case as under:-

i. The firm will recall the batch No. H-07616 from the market on immediate basis and area FID will supervise the destruction.
ii. To suspend the Registration of "Ann-vil Injection, Reg. No.012083" for six (06) months.
iii. To conduct PSI (Product Specific Inspection) to identify the root cause of manufacture of substandard product, and investigate with reference to product in question by a panel comprising of following members:
    a. Additional Director, QA & LT, DRAP, Islamabad.
    b. Director, DTL, Lahore
    c. Area FID
iv. The area FID will conduct sampling of Ann-vil Injection at resumption of production and send for test/analysis.

That the above said decision of 270th meeting of Registration Board was communicated to the firm vide reference No.F.03-28/2016-(QC) dated 13-07-2017. Reminder of the same was issued dated 07-12-2018.
Ms Venus Pharma, Lahore vide reference No. nil dated 24th February, 2019 referred DRAP, Islamabad letter No. 03-28/2016-(QC) and requested for change in the inspection panel for the said PSI.

Proceeding and decision of 289th meeting of Registration Board.

The case was presented before the Registration Board in its 289th meeting on 16th May, 2019 for reconstitution of the panel which was constituted by the Board in its 270th meeting and the Board reconstituted the panel as follows;

c) Director, Drug testing Laboratory, Lahore.
d) Area Federal Inspector of Drugs.

Case No.06: Manufacture & Sale of Sub-Standard Kawach Gel Batch No. KWI-4116 By M/S Lomus Pharmaceuticals (Pvt) Ltd, Nepal.

ADC-II, DRAP, Karachi inspected the premises of M/s Jhpiego, H. No. D-66 Block-II, Kehkashan Clifton, Karachi on 29-03-2017 and drew the sample of Kawach Gel Batch No. KWI-4116 having Expiry Date **August, 2019** mentioned on Form 3 manufactured by M/S Lomus Pharmaceutical Nepal imported by M/s Jhpeigo, karachi. Details are as under:

Name of Drug	Batch No.	Mfg. Date	Exp. Date	Manufactured by
Kawach Gel (Chlorhexidine)	KWI-4116	Sep-16	Aug-19	M/s Lomus Pharmaceutical Nepal

The above said sample has been declared as of Substandard quality by the Federal Government Analyst, CDL, Karachi on the basis of assay content **(Determined percentage – 111.8%, Limits – 90-110%, USP-40)** vide their test report No.KQ.213/2017 dated 15th June, 2017.

In the light of the above test report of Federal Government Analyst, CDL, Karachi explanation letters of reference No.F.DMK-15-18/2017-ADC-II (K) dated 21-06-2017 & 17-07-2017 were issued to M/s Jhpiego H. No. D-66 Block-II, Kehkashan Clifton, Karachi for explaining their position in the matter of importing and distribution of above mentioned substandard drug with the direction to recall the above said substandard drug/batch from the market.

M/s Jhpiego H. No. D-66 Block-II, Kehkashan Clifton, Karachi submitted their reply vide reference No.JP/NOC/DRAP-002/17 dated 23-06-17 & reference No.JP/NOC/DRAP-003/17 dated 21-07-17 wherein they have stated that from 16 districts of Sindh all 78,000 chlorhexidine 10gm tubes from B#4116 identified & 67612 are collected back, stored at their out sourced storage place and also requested for retesting from appellate laboratory, NIH, Islamabad as provided under section 22 of the Drugs Act, 1976.

As per request of the firm, the sample was sent to appellate laboratory, NIH, Islamabad dated 25-09-2017. The Appellate laboratory, NIH, Islamabad, vide test report No.019-M/2017 dated 06th November, 2017 declared the above said sample **Misbranded** as Urdu version of language, Registration number, local place of business, agent, indenter or distributor is neither mentioned on the immediate pack nor on the outer carton which is violation of packing and labeling rules of the Drugs Act, 1976.

The Assistant Director-II, DRAP, Karachi was requested to investigate the matter thoroughly and provide the details of SRO under which this donation was allowed to import for public use and clarify whether the labeling rules are applicable in this case or not vide letter F.No.3-37/2017-(QC) dated 05th January, 2018.

Assistant Director-II, DRAP, Karachi vide reference No.F.DMK-15-18/2017-ADC-II (K) dated 09-01-2018 provided the document including SRO 577(I)/2016 along with NOC/permission granted to import the 1st batch (150,000) units of the drug 7.1% Chlorhexidine Digluconate gel Release Chlorhexidine 4% W/W 10 gram tubes from M/s Lomus Pharmaceutical, limited Nepal. The NOC is not related to the Batch from which sampling was done by Assistant Director-II, Karachi, DRAP. The details are as under:

s. no.	**Particulars**	**Exp. Date**	**Category**	**Quantity**
1	Chlorhexidine gel 4% w/w	**Aug. 2017**	Medicine	150,000
Total				**150,000**

Assistant Director-II, DRAP, Karachi submitted that NOC for the consignment was issued by the office according to the SRO. 577(I)/2016 in accordance with the approved guidelines by the DRAP. Moreover it was also submitted that the above drug was imported as donation for supply

to Government of Sindh under Maternal and Child Health Program (MCHIP) as free of cost to needy patients. Hence labeling and packing Rules are not applicable for such import according to the above mentioned SRO.

Assistant Director-II, DRAP, Karachi was once again requested, vide letter F.No.3-37/2017-QC dated 30th January, 2019 to provide the NOC/clearance certificates including fair copy of application mentioning the Batch number and quantities of the subject cited drug along with other supporting documents, if any along with complete case with clear and candid recommendations for consideration of the Registration Board.

Assistant Director, DRAP, Karachi vide reference No.F.DMK-15-18/2017-ADC-II (K) dated 14th February, 2019 & No.F.DMK-15-18/2017-ADC-II (K) (377) dated 21st March, 2019 submitted the complete case for consideration of the Registration Board wherein ha has stated that consignment was imported as donation for supply to the Government of Sindh under Maternal and Child Health Integrated Program (MCHIP) hence labeling and packaging rules are not applicable for such import. He further added that No foreign exchange is involved as no payment has been made by M/s Jhpiego Clifton Karachi invoice amount only for custom purpose. M/s Jhpiego Clifton Karachi supplied the Kawach Gel free of cost in MNCH Program Government of Sindh.

The Assistant Director DRAP Karachi recommended that M/s Jhpiego Clifton Karachi may be allowed to utilize the remaining stock of Kawach Gel i.e. 67708 tubes in MNCH Program Government of Sindh before its expiry.

During evaluation it was observed that 2 invoices are provided, one is from manufacturer M/s Lomus Pharmaceuticals dated 04-11-2016 and second ADC attested **commercial invoice** is from M/s Logenix dated 29-09-2016.

No NOC was issued by DRAP Karachi for clearance of the consignment. An NOC vide No. F.3-8/2014-I&E (Vol-I) dated 11-03-2016 was issued by DRAP Islamabad for clearance of 150,000 units only where as in actual 250,000 units were cleared.

Proceeding and Decision:

The Board after perusing the record/ document of the instant case deliberated that the instant case is of unregistered drug and does not come under preview of the Registration Board as the Registration Board deals with the cases of registrar drugs referred by FID under sub rule (2) of rule (4) of the Drugs (Federal Inspectors, Federal Drug Laboratory & Federal Government Analysts) Rules, 1976. Moreover, as case pertains to donation of un-registered drugs permitted under special SRO thus it would be appropriate that licensing authority under Drugs (Import & Export) Rules, 1976 may decide the case.

Case No.07: Manufacture & Sale Of Adulterated & Sub-Standard "Oxytocin Injection (for vetonly)"Batch No. 2876 Manufactured By M/S. Elko Organization Pvt, Ltd, Karachi.

The matter of Adulterated and Substandard Oxytocin Injection Batch no 2876 manufactured by M/s Elko organization, Karachi, by CDL, Karachi vide report no. KQ.461/2014(B) dated 26th November, 2014, was placed before the Registration Board in its 248th meeting and RB decided as under:

I. Suspended the registration of oxytocin injection, registration no. 011122 of M/s Elko Organization (Pvt), Ltd, Karachi for a period of six months.

II. Investigation through a Product Specific inspection (PSI) by a panel comprising of director DTL Quetta, Chief Drug Inspector, Sindh and Area FID karachi.
III. The panel will also witness the destruction of the recalled/withheld stocks of the drug under reference.

That the letter regarding PSI was conveyed to panel members vide letter no. 3-56/2014-QC dated 22nd April, 2015. It was requested to conduct PSI by the panel members as under:

I. Dr. Amanullah Khan, Director, Drug Testing Laboratory, Quetta.
II. Syed Kalb-e- Hasan Rizvi, Chief Drug Inspector, Sindh.
III. Abdul Rasool sheikh, Area FID, Karachi.

That the reminders were issued to Additional Director, DRAP, Karachi to conduct PSI and submit the report by panel vide letter no. 3-56/2014-QC dated 9th October, and 26th October, 2017.

PSI report received from Additional Director, DRAP, Karachi vide F. no. 01-04/2017-DRAP(K)(Insp) dated 15th November, 2017 received on 23rd November, 2017 wherein he enclosed the detailed PSI report (duly signed) conducted by panel vide f. ARS.000245/2015-FID-III(k) dated 15th November, 2017.The panel members are as under:

I. Dr. Amanullah Khan, Director, Drug Testing Laboratory, Quetta.
II. Syed Kalb-e- Hasan Rizvi, Chief Drug Inspector, Sindh.
III. Abdul Rasool sheikh, Area FID, Karachi.

That the following points in the report submitted by Additional Director, DRAP, Karachi are as under:

- **Good practices in production**: The root cause of failure was rubber stopper which was not washed properly as rubber stoppers were being washed manually. Factors triggering such incidents were reviewed in detail. Keeping in view the instant failure stringent checking was found in place to avoid the occurrence and recurrence of such failures in future.
- **QA system**: with respect to the subject case their SOPS regarding failures and controlling the deviation were reviewed in detail. After receiving the report the firm had started to find out the root cause of the problem and total three batches were also investigated. The firm was found capable enough to investigate their failures as per SOPs. Appropriate in process checks were noted in place.

That the conclusion of the report submitted by panel is reproduced as under:

After investigating the root cause analysis (RCA) of the failure and subsequent rectification of the problem the firm had resumed the manufacturing of oxytocin injection after the lapse of suspension period and keeping in view the current status of their compliance the panel recommends that the firm may be allowed to continue the manufacturing of oxytocin injection. The panel further observed that the retained stocks in quarantine were destructed as per their approved SOP on 01.11.2016.

- Meanwhile, it is pertinent to mention that FIA Karachi is conducting enquiry 22/2017 on the complaint of Provincial Inspector of Drugs, Karachi about illegal import of oxytocin and manufacturing of oxytocin injections manufactured by M/s Elko organization, Karachi during suspension period. The FIA raised the following queries in this respect as under:

I. Copies of minutes of meeting of 248th Drug Registration Board where registration no. 011122 of M/s Elko organization Pvt., ltd was suspended.
II. Import details of oxytocin by M/s Elko Organization during 2015 to till date.

III. Procedure/ DRAP regulations to import oxytocin (in any form) into Pakistan by manufacturers of oxytocin for human and veterinary usage.
IV. Details of importers viz name of company, quantity imported, etc.
V. Details of any ban imposed on manufacturing or importing (in any form) of oxytocin by DRAP.

Similarly, NAB is also conducting an enquiry.

Proceeding and Decision of 278th Meeting of RB:

Product Specific Inspection report and import data forwarded by AD (I&E) DRAP Karachi about import of oxytocine raw material was contained by the DRB and discussed in details.

- The queries of the FIA Karachi and NAB were also brought in the knowledge of the Board members. The DRB after through deliberation decided as under:-
- That the company violated the orders of the DRB, statutory body and continued import of raw material during the suspension period as per detail are given below.
- The company resumed production of oxytocin vials without approval of the DRB.
- The Board decided to issue show cause notice & personal hearing letter to the firm for their violation in the forthcoming meeting.
- It was also decided that the Registration of the oxytocin shall remain suspended till final decision by the DRB in the forthcoming meeting.
- Registration Board advised PE&R Division to present the case regarding alleged use of oxytocin vials for enhancement of milk production in the animals.

The Board decided to issue show cause notices 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.

Proceeding and Decision of 281st meeting of DRB

Representatives of the M/s Elko appeared before the DRB and stated that M/s Elko did not manufactured oxytocin vials whose registration was suspended by the DRB. They manufactured 1cc injection of oxytocin which was also registered by the DRB. They further contented that after the expiry of suspension period they were legally authorized are manufacturing of oxytocin vials. DRB member law also opined that after the expiry of suspension period, the bar on the company is automatically revoked. The DRB after detailed deliberations and discussion constituted a Committee comprising of (Dr. Saif ur Rehman Khattak Director CDL Karachi and Additional Director Karachi) to investigate following issues:-

1. It shall be verified whether API of oxytocin vial for veterinary use and oxytocin ampoules for human use is of same specification as per their registration letters issued by the DRAP and cleared by the Karachi DRAP office during the suspension period.
2. The Quantity of oxytocin vials and oxytocin ampoules manufactured, sold and distributed during suspension period should be verified by the Committee after evaluation of manufacturing data of oxytocin vials and ampoules from the manufacturing and distribution records. Random verification should also be obtained from the distributors etc. past manufacturing trend of the oxytocin ampoules may also be taken into account while evaluating the manufacturing of oxytocin ampoules and vials during the suspension period
3. The Committee should submit its conclusive report for consideration of the Board with candid opinion whether M/s Elko conducted manufacturing of oxytocin vials during the suspension period of six months or not. It shall also be verified that the firm import of raw material was on the basis of oxytocin vials or oxytocin ampoules registrations.

4. Decision of cancellation of registration of Oxytocin vial in the light of show cause notice issued to the firm will be taken after the receipt of committee report.

Proceeding of 286th Meeting of Registration Board.

Inspection report is received on 05-10-2018 in response to DRAP, Islamabad letter No.03-56/2014-QC dated 12-06-2018 on the subject regarding "Investigation report on manufacturer and sale of adulterated and substandard Oxytocin injection (for vet only) Batch No. 2876 manufactured by M/s Elko Organization (Pvt.) Ltd., Karachi" wherein the finding of the investigation with respect to the scope are as under:

The committee mainly focused on the areas / issues as mandated to it by the Registration Board under the scope of this investigation.

A. <u>Official specifications of oxytocin raw material and registration of the firm</u>

1. Oxytocin injection has been used in humans as well animals. Monographs of oxytocin raw material and oxytocin injection are available both in United States Pharmacopeia and British Pharmacopeia. **The raw material of oxytocin for veterinary use has the same specifications as that for human use and the imported raw material of oxytocin was also of the same specifications. However, it also revealed that M/s Elko Organization (Pvt.) Ltd., Karachi does not hold registration of oxytocin ampoule for human use (undertaking of the firm attached as Annex-A).**

02. M/s Elko Organization (Pvt.) Ltd., Karachi holds following registrations of products containing oxytocin:

Name of product	Strength	Registration Numbers	Packing	Use
Oxytocin 5 I.U injection	5 I.U	011121	100x1ml ampoule	Veterinary Use
Oxytocin 10 I.U injection	10 I.U	011122	100x1ml ampoule	Veterinary Use
			50ml Vial	Veterinary Use
			100ml Vial (that was declared substandard)	Veterinary Use
XZ injection (Oxytocin 20 I.U)	20 I.U	085466	100ml	Veterinary Use

(Annex-B)

Upon cross checking of import documents pertaining to the period of suspension of the referred products i.e. (22-04-2015 to 21-10-2015) that were submitted in the DRAP, Karachi office for obtaining clearance including undertaking of the firm regarding utilization and Form-8 under Drug import & Export rules 1976 of the Drugs Act, 1976, **it was observed that the import of oxytocin was raw material was not made for oxytocin 10 I.U. (Annex-C).**

B. Oxytocin raw material import and manufacturing of oxytocin injection (10 I.U, 50/100ml vials and 100x1ml ampoules).

01. Review of oxytocin raw material import record:

- As per import and warehouse record of M/s Elko Organization (Pvt.) Ltd., Karachi following quantities of oxytocin were available/ received in the firm:

Sr. No.	LC No.	LC Date	Invoice No.	Invoice Date	Delivered On	Quantity (MIU)
	Opening balance on 23-04-2015					322.7
1	LC4731/15	13-13-2014	TM1504C007	07-04-2015	24-04-2015	500
2	CONT 12315	14-04-2015	RH20150520	20-05-2015	25-06-2015	100

3	LC 4833/15	10-04-2015	TM1505C012	12-05-2015	28-06-2015	500
4	LC 4595/15	16-02-2015	EXP/ELKO/15-16	25-062015	16-07-2015	300
5	CONT 17415	10-06-2015	ZY201506056	19-06-2015	16-07-2015	100
6	LC 5074/15	15-06-2015	TM150703C001	30-07-2015	11-08-2015	500
7	CONT 591/15	16-07-2015	ZY201508030	07-08-2015	27-08-2015	300
8	LC 5171/15	15-07-2015	TM150817C01	02-09-2015	10-09-2015	500
9	CONT 591/15	16-07-2015	ZY201508079	02-09-2015	29-09-2015	250
10	LC 2574/15	26-08-2015	TM150909M01	09-09-2015	05-10-2015	500
11	CONT 591/15	16-07-2015	Zy201509032	07-10-2015	07-10-2015	250
Total quantity MIU						**4122.7**

Related invoices and record attached as Annex-D

- The documents on the yearly planned for import show that 3800 MIU oxytocin raw material was imported during the suspension period with the undertaking of manufacturing of oxytocin containing registration product but not for product under suspension, as per pre established agreement of the firm for annual supply with the API manufacturers **(copies of bin cards attached as Annex-F).**

02. Review of purchase record of packing material (Glass vials, Glass ampoules, Rubber Stoppers, Al. Seals, Unicartons and Labels).

The purchase record related to the packing material of 50ml and 100ml oxytocin injection (10 IU vials) show that no purchase/ use of 50ml, 100ml vials, Al. Sealslabels and unicarton was made by the firm during the referred product suspension period. Since rubber stoppers for 50ml and 100ml are also used for other products therefore, rubber stoppers have been purchased during the referred product suspension period but for other registered products of the firm. Similarly no glass ampoules have been purchased by the firm during the suspension period. **(Copies of bin cards attached as Annex-F).**

03. Review of production record of oxytocin injection (50/100ml vials).

- Physical inspection of the manufacturing equipments and confirmation by the manufacturer **(copy attached as Annex-G)** establish that the manufacturer has the capacity of manufacturing oxytocin injection as under:

- Minimum batch size capacity = 600 liters (12,000 vials of 50ml 0r 6000 vials of 100ml)
- Maximum batch size capacity = 3000 liters (60,000 vials of 50ml or 30,000 vials of 100ml).
- Maximum filling/ packing capacity = 70,000 vials/ 8 hours.

The previous record of the production shows that before and after suspension period the firm has manufactured mainly 50ml and 100ml oxytocin vials in 10I.U. potency.

- The scrutiny of production record i.e. raw material bin cards, daily production record, finished goods store bin cards etc. (copies attached as Annex-H) revealed that M/s Elko Organization did not conduct manufacturing of oxytocin products (the product suspended and oxytocin product whose registrations were valid) in the section of the firm during the suspension period i.e. 22-04-2015 ton 21-10-2015.

04. Review of quality control and quality assurance documents and record.

As per record of QC (Test/ analysis reports) and instruments utilization log books and tests log books the production and testing of the referred product could not be establish during the suspension period. The assay (potency) test of oxytocin injection is based on HPLC method as per United States Pharmacopeia therefore the specific HPLC (Shemadzu, LC-20AT) system

was also checked for audit trial for the same. Although proper audit trial was not available on the instrument, however, the available data on the instrument show that no batch of oxytocin injection was tested on the instrument during the suspension period **(copies of log book attached as Annex-I).**

The quality assurance record show that no batch number of the referred product was issued nor any new batch history record reviewed / authorized during the suspension period.

C. Review of sales record.

The firm has selling their veterinary products through their sole authorized agent for sale/distribution with the name and address as under:

M/s Shaheen Enterprises, Road No.9, Cattle Colony, Bin Qasim Town Karachi (**Copies of appointment of the distributor and related documents attached as Annex-J**).

As per record related to sale available at factory premises and at M/s Shaheen Enterprises, the sale/purchase of the referred product could not be established for the period of suspension other than the batches which were manufactured before suspension period **(copies of the sale record attached as Annex-K).**

D. Feedback from employees at manufacturing and sale premises.

The following employees/personnel were asked specifically for related information to assist the investigation process and to authenticate the record provided:-

S.No	Name of Technical person	Designation
1.	Mr. Muhammad Farooq	Plant Manager (DRAP approved person for production)
2.	Mr. Muneer Ahmad	QC Manager (DRAP approved person for QC)
3.	Ms. Shama Anees	Production Manager
4.	Ms. Leena Baig	Production Officer, Injection Section
5.	Mr. Mirza Ayaz Baig	Quality Operation Manager
6.	Ms. Syeeda Mahwish	QC Microbiologists
7.	Mr. Muzaffar Nawab	Raw Material Store Incharge
8.	Mr. Muhammad Ali	Finished Goods Store Incharge
9.	Mr. Tahir Javed	Proprietor Shaheen Enterprises

As per statement attached of the technical persons the production of any of the Oxytocin strength was not conducted (**copies attached as Annex-L).**

Conclusion

Keeping in view of the investigation, through scrutiny/review of record pertaining to the Import of Oxytocin Raw Material, production of Oxytocin products, quality control, storage, sales and distribution of 10 IU Oxytocin Injection, physical inspection of manufacturing, storage and distribution/retail sale site/outlets, examination of log books related to equipment/instrument utilization and processes and information/feedback gathered from related people it is concluded:

a. the firm has imported 3800 IU Oxytocin Raw Material (USP Grade) during the suspension period for utilization in 5 IU (Registration No.011121, 100x1ml ampoules packs) however, as per record the material was not utilized till 12.01.2016 i.e. resumption of 10 IU 50ml and 100 ml vials (Registration No.011122) production.

b. That, production of the Oxytocin vial 10 IU (100 ml) could not be established during the suspension period.

c. Firm resumed production by their self after the expiry of the suspension period i.e. 22.04.2015 to 21.10.2015.

d. The committee is also of the opinion that the necessary sale record could be verified in detail, if necessary, through provincial health authorities because of availability of adequate field force.
e. The committee also recommends that necessary directions may please be issued to the firm for availability of 21 CFR compliant equipments/ instrument in the QC Lab for audit trail purposes.

Decision:

The board considered the report of the committee and after deliberation, the Board decided as under:

1. The registration of oxytocin vial shall remain suspended till the final decision by the Registration Board about the cancellation of registration of multi dose oxytocin vials in the light of show cause notices approved by the RB. Its fate will be decided collectively as a policy decision.
2. The provincial governments shall be requested to verify the sales data of oxytocin vials during the suspension period (22-04-2015 to 21-10-2015) of oxytocin which is subject matter. The sales data oxytocin ampoules shall also be verified that was sold by M/s Elko Organization during the said period.
3. Certified copy of the List of Distributors and sales and distribution data of the oxytocin vials and ampoules will be obtained from the company through area FID.

That the above said decision was communicated to the firm vide letter No.F.03-86/2018-QC (286-RB) dated 16th January, 2019 with direction to comply with the decision of the Registration Board. Reminder of the same was issued vide letter No.F.03-56/2014-QC dated 12th March, 2019.

That the area FID was once again requested to comply with the decision of the Registration Board vide letter No.F.03-56/2014-QC dated 12th March, 2019. Certified copy of the List of Distributors and sales and distribution data of the oxytocin vials and ampoules is yet awaited. Accordingly the verification of sales/distribution data could not be sent to the provincial authorities. The matter is already investigation by the NAN authorities and Mr. Sajjad Ahmad Abbasi has been nominated for assistance to Combined Investigation team headed by Mr. Saeed Ahmad Sheikh (CO-B) at investigation Wing-II, NAB, Karachi by the CEO, DRAP and communicated vide letter No.F.03-56/2014-QC dated 09th April, 2019 and 17th April, 2019.

It is recommended that the registration of the product may remain suspended until M/s Elko Organization cooperates and submits data for verification and the same also verified at ground level by the provincial authorities who are also complainant before the NAB and FIA.

Proceedings of 289th meeting of DRB:

The Board was appraised that the FID DRAP Karachi has forwarded partial data pertaining to M/s Elko organization (Pvt.) Ltd., Karachi vide F.No. 000245/2017-FID (K) dated 07th May 2019. Evaluation of this partial data reveals that it is only for 100ml vials only and Registration No. is also not mentioned. The data of other pack size i.e. 1ml ampoule and 50ml vial with Reg.No. 011122 is yet to be provided. The batch No. in the partial data before and after the resumption period is not in continuation.

The Board was further appraised that M/s Elko Organization (Pvt.) Ltd., Karachi has filed a Constitution petition No.D-562 of 2019 titled M/s Elko Organization (Pvt.) Ltd., Vs Federation of Pakistan & others in the High Court of Sindh at Karachi, which is fixed for hearing on 21-05-2019.

Decision:

The Board after perusing the record/ document of the instant case deliberated the matter in depth and decided as under:

- **That cancellation of registration of multi-dose oxytocin vials is a separate issue and shall be decided by the Registration Board separately as a policy decision.**

- **Suspension of oxytocin 10 IU Injection (Reg.No. 011122) was not due to above issue rather due to manufacturing of Adulterated and Substandard Oxytocin Injection Batch No. 2876.**

- **That the firm M/s. Elko Organization (Pvt) Ltd., Karachi has three registration of oxytocin namely Oxytocin 5 I.U injection (Reg.No. 011121) in pack size of 100x1ml ampoule, Oxytocin 10 I.U injection (Reg.No. 011122) in pack size of 100x1ml ampoule, 50ml vial and 100ml vial and XZ Injection (Oxytocin 20 IU) (Reg.No. 085466) in pack size of 100ml.**

- **Registration Board has suspended Oxytocin 10IU Injection (Reg. No. 011122) in pack sizes of 100x1ml ampoule, 50ml vial & 100ml vial. The other two products Oxytocin 5 I.U injection (Reg.No. 011121) and XZ Injection (Oxytocin 20 IU) (Reg.No. 085466) have not been suspended.**

- **Registration Board is investigating the manufacturing of Oxytocin 10 IU Injection (Reg.No.011122), in pack size of 100x1ml ampoule, 50ml vial and 100ml vial during suspension period (22-04-2015 to 21-10-2015).**

- **Sales data of Oxytocin 10IU injection (Reg.No. 011122) in pack size of 100x1ml ampoule, 50ml vial and 100ml vial is to be verified from Provincial Governments after provision of same along with list of distributors from M/s Elko Organization.**

- **The product Oxytocin 10IU injection (Reg.No. 011122) in pack size of 100x1ml ampoule, 50ml vial and 100ml vial shall remain suspended till verification of sales data.**

- **A report with above status shall be presented before the Honorable Sindh High Court on next date of hearing.**

Additional Agenda

A. Biological Drugs Division:

1. 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 and godown for already registered human biologicals as per following details:

Sr. No.	Reg. No.	Product Name	Date of Initial Registration	Date of Last renewal Submission	Previous Address of Importer	New Address of Importer
1.	043004	Avastin 100mg/4ml	22-03-2006	21-03-2016	37-C, Block 6, P.E.C.H.S., Karachi	1st Floor, 37-B, Block 6 PECHS, Karachi
2.	043005	Avastin 400mg/16ml	22-03-2006	21-03-2016		
3.	032130	Herceptin 440mg Vial	04-08-2004	28-07-2014		
4.	032131	Solvent for Herceptin 440mg	04-08-2004	28-07-2014		
5.	059052	Mircera Injection 50mcg	02-09-2009	28-08-2014		
6.	059051	Mircera Injection 75mcg	02-09-2009	28-08-2014		
7.	059050	Mircera Injection 100mcg	02-09-2009	28-08-2014		
8.	059049	Mircera Injection 150mcg	02-09-2009	28-08-2014		
9.	059048	Mircera Injection 200mcg	02-09-2009	28-08-2014		
10.	019576	Recormon 2000 Inj.	26-03-1998	29-01-2018		
11.	019577	Recormon 5000 Inj.	26-03-1998	29-01-2018		
12.	019578	Recormon 10000 Inj.	26-03-1998	29-01-2018		
13.	031394	Ristova 100mg/10ml	28-02-2013	12-01-2018		
14.	031395	Ristova 500mg/50ml	28-02-2013	12-01-2018		
15.	077512	Ropegra	19-09-2013	29-08-2018		

The firm has submitted following documents;

i. Fee of Rs. 5000/- for each product.
ii. Copy of registration lettersand last renewal submissions.
iii. Copy of valid DSL for new address.

In this context, it is submitted that the last renewal applications of products at sr. 5 to 15 are available in this division and were submitted in time while for products at sr. no. 3 to 4, the original renewal applications have been provided by RRR and for products at sr. 1 to 2, the RRR section provided the copies of renewal submissions and verified that the renewal applications were submitted in time.

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."

The tabulated detail is as under:

Address of Head Office as per new DSL	Addresses of godowns as per new DSL
1st 37-B, Block 6 PECHS, Karachi	i. R-PI, Plot No. 116, Sector 15, K.I.A, Karachi. ii. 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.**

2. Appeal Filed by M/s MarushPvt Ltd.,Lahore in the Appellate Board against the decision of Registration Board taken in 287th meeting held on 3rd & 4th January, 2019.

M/s MarushPvt. Ltd. Lahore filed the appeal in the Appellate Board against the decision of the Registration Board whereby the Registration Board refused to confirm the renewal status of following products registered in the name of M/s MarushPvt. Ltd., Lahore:

Sr#	Reg. No.	Name of Product
1.	039911	Cevac Broiler ND K Vaccine
2.	039910	Cevac Transmune IBD Vaccine
3.	022799	Cevac ND IB EDS K Vaccine
4.	022796	Cevac ND IBD K Vaccine
5.	022792	Cevac ND IB K Vaccine

The decision of the Registration Board is reproduced below:

Decision of Registration Board (287th meeting) held on 3rd & 4th January, 2019:

"During the deliberations Registration Board observed that the firm is involved in import of unregistered drugs, used of forged registration letters and various clearance authorization by DRAP and accordingly a number of cases are under investigations including 02 FIRS at various levels in FIA and custom authorities against M/s Marush International and M/s Marush (Pvt) Ltd and its owners, as follows:

a) Custom authorities / FBR have registered FIR No.05/2017 at Lahore which is under investigation as per report of DRAP Lahore office regarding illegal import of poultry medicines / vaccines by presenting fake / irrelevant provisional authorizations of the DRAP. Along with other allegations of massive mis-declaration of values by suppressing the actual transactional value and transfer of foreign exchange. DRAP Karachi has confirmed that fake registrations letters purported to be issued by DRAP were prepared and presented before the custom authorities for the release of unregistered therapeutic goods from the custom authorities since 2010-2015 and the matter is under investigation

b) FIA inquiry No.21/2017 of FIA Corporate Crime circle, Karachi is also under investigation against M/s Marush (Pvt) Ltd and Marush International alleging that Director / CEO of the said companies committed fraud / evasion of taxes which cause heavy loss to government exchequer. In light of aforementioned inquiry of FIA, DRAP has also requested for registration of an FIR u/s 420, 467, 468, 471 and 472 of PPC with permission of Central Licensing Board.

Keeping in view above status, the Board decided as follows:

i. For issuance of registration letters of pending registrations:

The Board decided not to issue Registration letters till the completion of inquiries and finalization of legal proceedings including FIR as stated above and provision of latest sole agency agreement by M/s Marush Pvt. Ltd., Lahore for above new registrations from their manufacturer abroad/ principal.

ii. Renewal Status:

The Board decided that as the firm has also submitted incomplete applications in following aspects, thus the renewal status cannot be confirmed till completion of inquiries and finalization of legal proceedings including FIR as stated above and rectification of following deficiencies in renewal applications as mandatory requirement for issuance / confirmation of renewal status:

a. Form-5B signed by Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore OR Authority letter of the signing person.

b. An undertaking that the applied products has never been de-registered

c. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.

d. Attested copy of registration letter for confirmation of brand name.

e. Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore.

f. Attested copy of valid Drug Sale License (for imported drugs)

g. Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products)

h. Inspection report by regulatory authority of country of manufacture.

i. Last import invoice attested by DRAP."

The Decision of 152nd sitting of the Appellate Board held on 24th & 25th April,2019:

Now the appeal of the M/s Marush Pvt. Ltd. Lahore has been disposed of by the Appellate Board and regarding renewal application the decision of the Appellate Board is reproduced as under:

"Since the appellant could not remove the above deficiencies pointed out by the Registration Board till date which cannot be relaxed for the appellant under any circumstances, the appellant is directed to remove deficiencies pointed out in impugned decision dated 10-01-2019 and submit following documents to the Secretary , Registration Board within 10 days of the receipt of this decision for consideration of renewal status of its products by the Registration Board.

a) Form-5B signed by Chief Executive Officer of M/s Marush Pvt Ltd., Lahore OR Authority letter of the signing person.

b) An undertaking that the applied products has never been de-registered

c) An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.

d) Attested copy of registration letter forconfirmation of brand name.

e) Attested copy of approval letter of transfer of registration in name of M/s MarushPvt. Ltd., Lahore.

f) Attested copy of valid Drug Sale License (for importeddrugs)

g) Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products)

h) Inspection report by regulatory authority of country ofmanufacture.
i) Last import invoice attested by DRAP.
j) Copy of valid sole agency agreement

Present Status:

In compliance of the above decision of the Appellate Board the firm has submitted that the he had made an application for registration of its products strictly in accordance with law prevalent at the time of submission of the aforesaid application on 24-03-2016 in terms of Rule 26(3)(c) of the Drugs (Licensing, Registering & Advertising) Rules 1976 and on the contrary the new SOPs formulated in the 276th meeting of Registration Board held on 22nd -25th November,2017,can by no stretch of the imagination be applicable on the Company's pending application. Further has been stated that it is the dictum laid down by the superior courts that policies such as SOPs that are promulgated or formulated after a Company has duly made its application cannot applied upon the same retrospectively. The letter of the firm is reproduced below:

1. "We write to your good self on behalf of MarushPvt. Ltd (the "Company") for compliance of the order dated 26-04-2019 of the Drugs Appellate Board passed in its 152nd Meeting held on 24th and 25thApril, 2019.

Copy of the decision dated 26-4-2019

2. Previously the Company had challenged the decision dated 10-01-2019 passed by the Registration Board whereby our application for renewal of registration for seventeen products was declared as incomplete on the basis of certain documentary deficiencies.
3. At the very outset it is submitted that the Company had made an application for registration of its products strictly in accordance with law prevalent at the time of submission of the aforesaid application on 24-03-2016 in terms of Rule 26(3)(c) of the Drugs (Licensing, Registering & Advertising) Rules 1976.
4. On the contrary the new SOPs formulated in the 276th meeting of Registration Board held on 22nd -25th November,2017,can by no stretch of the imagination be applicable on the Company's pending application before your good self. It is the dictum laid down by the superior courts that policies such as SOPs that are promulgated or formulated after a Company has duly made its application cannot applied upon the same retrospectively.
5. It may be noted that the Company has conducted its business in compliance with all applicable laws including the Drugs Act, 1976 and the Drugs (Licensing Registering Advertising) Rules 1976 and received no complaint from any quarter whatsoever.
6. Since, the Company's appeal before the Drugs Appellate Board has been rejected the following documents are being submitted as directed in decision dated 24-04-2019 under protest:
   i. Form-5B signed by CEO of Marush (Private) Limited / its authorized person (original already submitted on 24-03-2016) alongwith its receivings.
   ii. Legalized CoPP as per WHO's format or legalized free sales certificate and GMP certificate (for imported products) (already submitted for the relevant products on 24-03-2016) alongwithreceivings.
   iii. An undertaking that the applied products have never been de-registered.
   iv. An undertaking the the submitted documents are true copies of the originals and that the Company may be held responsible in case of any discrepancy/misinformation as per the relevant laws.

v. Attested copy of the registration letter for confirmation of brand name
vi. Attested copy of approval letter of transfer of registration from EVP to Marush (Pvt) Ltd
vii. Attested copy of valid Drug Sales License
viii. Inspection report by regulatory authority of the manufacturer
ix. Last import invoice attested by DRAP
x. Copy of valid Sole Agency Agreement of the manufacturer

7. Without prejudice, to the Company's compliance with the decision of the Drugs Appellate Board the same reserves the right to challenge the decision dated 24-04-2019 before a court of competent jurisdiction.
8. In light of submission of these documents, thanks to release our shipment of vaccines lying at Lahore Airport, which is losing valuable shelf life every day, is incurring heavy demurrage charges on daily basis and is at risk of damage due to breakage of cold chain due to limited storage in the Lahore Airport's cold storage, as we have received several reminders from Gerry's Dnata Pvt Ltd, till date.
9. In view of the foregoing, your office is requested to kindly accept the enclosed documents and issue the Company a receipt of the same in accordance with law."

The firm submitted documents have been evaluated and summarised as under:

i. Cevac Broiler ND K Vaccine

Sr. No.	Deficiencies to be removed by the firm as per Decision of the Appellate Board	Documents/Reply submitted by	Remarks
a.	Form-5B signed by Chief Executive Officer of M/s MarushPvt. Ltd., Lahore OR Authority letter of the signing person.	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	Name and Designation of Signatory is not mentioned on Form-5-B.
b.	An undertaking that the applied products has never been de-registered	Provided	Undertaking is given on the letter head of the firm.
c.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.	Provided	Undertaking is given on the letter head of the firm.
d.	Attested copy of registration letter for confirmation of brand name.	Provided	
E	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore	Provided	
f.	Attested copy of valid Drug Sale License (for imported drugs)	Provided	
g.	Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products)	The firm has submitted that they have already submitted for all products under question on 24-03-2016.	The original application of the renewal submitted on 24-03-2016 vide diary No.1360 present with this division **does not have Legalized CoPP or**

		(Copies of receiving Enclosed)	**legalized free sale certificate and GMP certificate rather submitted only copies of FSC & GMP** of the respective products.
h.	Inspection report by regulatory authority of country of manufacture.	Provided	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
i.	Last import invoice attested by DRAP.	Provided	Not Provided
j.	Copy of valid sole agency agreement	Provided	
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do			

ii. Cevac Transmune IBD Vaccine

Sr. No.	Deficiencies to be removed by the firm as per Decision of the Appellate Board	Documents/Reply submitted by	Remarks
a.	Form-5B signed by Chief Executive Officer of M/s MarushPvt. Ltd., Lahore OR Authority letter of the signing person.	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	Name and Designation of Signatory is not mentioned on Form-5-B.
b.	An undertaking that the applied products has never been de-registered	Provided	Undertaking is given on the letter head of the firm.
c.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.	Provided	Undertaking is given on the letter head of the firm.
d.	Attested copy of registration letter forconfirmation of brand name.	Provided	
E	Attested copy of approval letter of transfer of registration in name of M/s MarushPvt. Ltd., Lahore	Provided	
f.	Attested copy of valid Drug Sale License (for importeddrugs)	Provided	
g.	Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products)	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	The original application of the renewal submitted on 24-03-2016 vide diary No.1360 present with this division **does not have Legalized CoPP or legalized free sale certificate and GMP certificate rather submitted only copies of FSC & GMP** of the respective products.

h.	Inspection report by regulatory authority of country of manufacture.	Provided	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from EudraGMP website vide link given below *
i.	Last import invoice attested by DRAP.	Provided	Not Provided
j.	Copy of valid sole agency agreement	Provided	
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do			

iii. Cevac ND IB EDS K Vaccine

Sr. No.	Deficiencies to be removed by the firm as per Decision of the Appellate Board	Documents/Reply submitted by	Remarks
a.	Form-5B signed by Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore OR Authority letter of the signing person.	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	Name and Designation of Signatory is not mentioned on Form-5-B.
b.	An undertaking that the applied products has never been de-registered	Provided	Undertaking is given on the letter head of the firm.
c.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.	Provided	Undertaking is given on the letter head of the firm.
d.	Attested copy of registration letter forconfirmation of brand name.	Provided	
E	Attested copy of approval letter of transfer of registration in name of M/s MarushPvt. Ltd., Lahore	Provided	
f.	Attested copy of valid Drug Sale License (for importeddrugs)	Provided	
g.	Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products)	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	The original application of the renewal submitted on 24-03-2016 vide diary No.1360 present with this division **does not have Legalized CoPP or legalized free sale certificate and GMP certificate rather submitted only copies of FSC & GMP** of the respective products.
h.	Inspection report by regulatory authority of country ofmanufacture.	Provided	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of

			GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from EudraGMP website vide link given below *
i.	Last import invoice attested by DRAP.	Provided	Not Provided
j.	Copy of valid sole agency agreement	Provided	
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do			

iv. Cevac ND IBD K Vaccine

Sr. No.	Deficiencies to be removed by the firm as per Decision of the Appellate Board	Documents/Reply submitted by	Remarks
a.	Form-5B signed by Chief Executive Officer of M/s MarushPvt. Ltd., Lahore OR Authority letter of the signing person.	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	Name and Designation of Signatory is not mentioned on Form-5-B.
b.	An undertaking that the applied products has never been de-registered	Provided	Undertaking is given on the letter head of the firm.
c.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.	Provided	Undertaking is given on the letter head of the firm.
d.	Attested copy of registration letter forconfirmation of brand name.	Provided	
E	Attested copy of approval letter of transfer of registration in name of M/s MarushPvt. Ltd., Lahore	Provided	
f.	Attested copy of valid Drug Sale License (for importeddrugs)	Provided	
g.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products)	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	The original application of the renewal submitted on 24-03-2016 vide diary No.1360 present with this division **does not have Legalized CoPP or legalized free sale certificate and GMP certificate rather submitted only copies of FSC & GMP** of the respective products.
h.	Inspection report by regulatory authority of country ofmanufacture.	Provided	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted

			with inspection report has been verified from EudraGMP website vide link given below *
i.	Last import invoice attested by DRAP.	Provided	Provided
j.	Copy of valid sole agency agreement	Provided	
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do			

v. Cevac ND IB K Vaccine

Sr. No.	Deficiencies to be removed by the firm as per Decision of the Appellate Board	Documents/Reply submitted by	Remarks
a.	Form-5B signed by Chief Executive Officer of M/s MarushPvt. Ltd., Lahore OR Authority letter of the signing person.	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	Name and Designation of Signatory is not mentioned on Form-5-B.
b.	An undertaking that the applied products has never been de-registered	Provided	Undertaking is given on the letter head of the firm.
c.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws.	Provided	Undertaking is given on the letter head of the firm.
d.	Attested copy of registration letter forconfirmation of brand name.	Provided	
E	Attested copy of approval letter of transfer of registration in name of M/s MarushPvt. Ltd., Lahore	Provided	
f.	Attested copy of valid Drug Sale License (for importeddrugs)	Provided	
g.	Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products)	The firm has submitted that they have already submitted for all products under question on 24-03-2016. (Copies of receiving Enclosed)	The original application of the renewal submitted on 24-03-2016 vide diary No.1360 present with this division **does not have Legalized CoPP or legalized free sale certificate and GMP certificate rather submitted only copies of FSC & GMP** of the respective products.
h.	Inspection report by regulatory authority of country ofmanufacture.	Provided	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from EudraGMP website vide link given below *
i.	Last import invoice attested by DRAP.	Provided	Not Provided
j.	Copy of valid sole agency agreement	Provided	

At the end the firm has requested to release their shipment of vaccines lying at Lahore Airport which is losing valuable shelf life every day and is at risk of damage due to breakage of cold chain due to limited storage in the Lahore Airport's cold storage.

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

a. **Form-5B for each product signed by Chief Executive Officer of M/s Marush Pvt Ltd., Lahore OR Authority letter of the signing person.**
b. **Valid legalized CoPP or FSC issued by regulatory body of country of origin.**
c. **DRAP attested last import invoice of Cevac Broiler ND K Vaccine, Cevac Transmune IBD Vaccine, Cevac ND IB EDS K Vaccine and Cevac ND IB K Vaccine.**

3. Minutes of3rd Meeting of Committee on Biological Drugs constituted by Registration Board in its 273rd meeting held on 29th April, 2019.

3rd meetings of committee on Biological drugs constituted by Registration Board in its 273rd meeting was held on29thApril, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was attended by the following:-

1.	Maj.Gen.Dr. Tahir Mukhtar Syed	Chairman
2.	Dr. Noor us Saba, Director Biological Drugs	Member
3.	Dr.Qurban Ali, Member Registration Board	Member
4.	Mr. Abdullah Add. Director (PE&R) / Secretary Registration Board	Co-Opted Member
5.	M. ZubairMasood, Asst. Director, Biological Drugs	Secretary

Mr. Khurrum Khalid AD (Bio) and Mr. Saadat Ali Khan AD (Bio) assisted with relevant agenda. Mr. NadeemAlamgirreperesentedPharma Bureau while not any representative of PPMA and PCDA attended the meeting. Mr. AjmalNasir (BF Biosciences) was called for on his request with the permission of Chairman as the firm is not member of PPMA.

Division of Biological Evaluation & Research has received many applications for registration of Enoxaprin Injections where the bulk will be imported and packed locally. Registration Board in its 281st meeting, while discussing the cases of imported Enoxaprin Injections, decided as follows:

"Registration Board deliberated the matter in detail and decided that for registration of Enoxaparins the applicants shall provide the following data/information with application:

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*
v. *Certain aspects of the drug's effect in humans."*

For local manufacturing of Enoxaparin injections Registration Board in its 28thmeeting referred the case to Committee on Biological Drugs constituted in 273rd meeting to make guidelines for registration of locally manufactured Enoxaparin injections.

In this context, division of BE&R found two approaches for registration of generic/ biosimilarEnoxaprin injections. One is adopted by USFDA which is called as Abbreviated New

Drug Application (ANDA) while the other is adopted by other reference countries like EMA, TGA Australia & Health Canada etc. The USFDA approach for registration of Enoxaparin Injection was adopted by Registration Board in its 281st meeting for registration of imported Enoxaparin Injections. Both approaches are detailed below:

Guidelines of FDA:

In the United States, innovator LMWHs are classified as drugs under the New Drug Application (NDA) process. The abbreviated NDA (ANDA) requires the demonstration of bioequivalence through pharmacokinetic (PK) studies. The approval of the first generic LMWH enoxaparin followed this pathway.The approval of ANDAs for enoxaparin raises complicated scientific and regulatory issues, which the FDA carefully considered. The FDA concluded that an ANDA applicant for enoxaparin can demonstrate active ingredient sameness by meeting 5 criteria, each of which captures different aspects of the active ingredient's ''sameness.''

The 5 criteria involve:

(1) The physical and chemical characteristics of enoxaparin

(2) The nature of the source material and the method used to break up the polysaccharide chains into smaller fragments

(3) The nature and arrangement of components that constitute enoxaparin

(4) Certain laboratory measurements of anticoagulant activity

(5) Certain aspects of the drug's effect in humans.

The equivalence evaluation demonstrates that the molecular diversity of the generic drug product's enoxaparin and branded enoxaparin is equivalent, including with respect to the 1,6anhydro ring structure at the reducing ends between 15% and 25% of its saccharide units. Equivalent molecular diversity demonstrated sameness for the generic version of enoxaparin.

The term ''same as'' means ''identical in active ingredient/ ingredients.''The FDA specifically rejected the suggestion that active ingredients exhibit the same physical and chemical characteristics, that no additional residues or impurities can result from the different manufacture or synthesis process, and that the stereochemistry characteristics and solid state forms of the drug have not been altered. Instead, FDA adopted a more flexible approach considering an active ingredient (in a generic drug product) to be the same as that of the reference listed drug (RLD) if it meets the same standards for identity. **The standards for identity are described in the United States Pharmacopeia (USP),** although FDA might prescribe additional standards that are material to the ingredient's sameness. In the case of enoxaparin, there is an **USP monograph** and there are additional standards that are material to enoxaparin's sameness.

1. The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).
2. The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The

equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.

3. The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.
4. The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.
5. The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.

They concluded that the rigorous chemical analyses will detect the antithrombin binding site of the generic LMWH, impurities leading to severe anaphylactoid reactions, and immunogenicity leading to heparin-induced thrombocytopenia type II (HIT-II). The FDA stated that it is not necessary to completely characterize all of the different polysaccharide sequences, nor is it necessary to use the same manufacturing process as that used for the RLD or to conduct clinical trials to demonstrate equivalent safety or effectiveness. The FDA regulations do not require that an ANDA applicant uses the same methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the RLD to assure and preserve the identity, strength, quality, and purity of the generic drug. The FDA concludes that ANDA applicants are not required to submit clinical trials to establish the safety and effectiveness of a generic LMWH if the 5 criteria see above are fulfilled.

Guidelines of the EMA:

The guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance—nonclinical and clinical issues (EMEA/CPMP/42832/ 05/)—lays down the general requirements for demonstration of the similar nature of 2 biological products in terms of safetyand efficacy. This product-specific guidance complements the above guideline and presents the current view of the Committee for Medicinal Products for Human Use (CHMP) on the application of the guideline for demonstration of biosimilarity of 2 LMWH-containing medicinal products.

1. Biochemical characterization
2. In vitro Pharmacodynamic studies
3. In vivo Pharmacodynamic studies
4. Data from at least 1 repeated dose toxicity study in a relevant species (e.g. the rat).

5. Phase I studies: The absorption and elimination characteristics of biosimilar LMWHs should be compared with thebranded LMWH by determining PD activities (including anti-FXa and anti-FIIa), as surrogate markers for their circulating concentrations.
6. Therapeutic equivalence should be demonstrated in at least 1 adequately powered, randomized, double-blind, parallel group clinical trial.
7. Prelicensing safety data should be obtained in a number of patients sufficient to determine the adverse effect profiles of the test medicinal product.
8. Demonstration of comparable efficacy and safety in surgical patients at high risk of VTE as recommended may allow extrapolation to other indications of the reference medicinal product if appropriately justified by the applicant.
9. A risk management program plan in accordance with the current EU legislation and pharmacovigilance guidelines.

In view of the above international guidelines, the guidelines adopted in 281st meeting of Registration Board for registration of imported Enoxaparins, the guidelines adopted for registration of locally manufactured rDNA therapeutic proteins and current scenario of Pakistan Division of BE&R is of the view that following guidelines may be considered for registration of locally manufactured & Imported Enoxaparin Injections:

Bulk Import, Locally Repacked Enoxaparins	**Finished Import Enoxaparins**
1. 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 oforigin. 2. 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 sameconcentrate/ready to fill bulk after submission of data to the concerned regulatoryauthority. 3. The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board 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 todemonstrate the similar efficacy and safety to innovator product. 4. The firm shall provide the lot release certificate of the finished product manufacturedby same bulk concentrate/ ready to fill from country of export (If applicable). 5. The firm shall provide the 6 months accelerated and real time stability studies for drugsubstance. 6. The local manufacturer shall manufacture three trial batches of the finished biologicalproduct to finalize the formulation and then perform all the tests as detailed in USP monograph of Enoxaparin Sodium in addition to tests for equivalence of disaccharide building blocks, fragment mapping, and sequence of	The applicant of finished import of Enoxaparin injections shall submit the data in light of decision of 281st meeting. The explanation of those 5 criteria is as follows: 1. The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS). 2. The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar. 3. The third criterion for demonstrating the sameness of enoxaparin is equivalence in

oligosaccharide species. All these testsshall be performed in comparison with innovator product. 7. The local manufacturer shall perform immunogenicity studies in comparison with Innovator product in order to confirm that the locally manufactured Enoxaparinis safe from heparin-induced thrombocytopenia type II (HIT-II). 8. The firm shall also provide the list of finished products being manufactured from samebulk concentrate or ready to fill form in any country of the world (if available). 9. 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 relevantdocuments. 10. Regular monitoring through pharmacovigilance reporting system shall be observedthrough proper pharmacovigilance cell of the manufacturer and report will beforwarded to the National Pharmacovigilance Centre, Division of Pharmacy Servicesand Biological Division of DRAP. In case of any severe adverse event, immediatemandatory reporting procedure shall be followed. 11. The firm shall inform DRAP if there shall be any adverse event or ADR reporting fromthe country of manufacture of concentrate/ready to fill bulk and finished product asrequired vide Rules 30 of Drug (LR&A) Rule. 12. If any of the conditions is not fulfilled or public health risk reported at any stage, thedrug registration shall stand cancelled with immediate effect. 13. All the provisions as contained in the Drugs Act, 1976 and rules made there underincluding provisions of Lot Release certification from National Control Laboratory forBiologicals shall be strictly adhered to. 14. For the already registered and approved drugs for local manufacturing the current guidelines shallapply**.**	disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included. 4. The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided. 5. The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles. In addition to above studies, the manufacturer abroad shall provide immunogenicity studies in comparison with Innovator product in order to confirm that said Enoxaparin is safe from heparin-induced thrombocytopenia type II (HIT-II**).**

Recommendations of the committee:

The committee while considering the statutory requirements and current scenario of Pakistan recommended the following:

i) For Bulk Concentrate Import, Local formulation Filling:

i. 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 oforigin.

ii. 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 sameconcentrate/ready to fill bulk after submission of data to the concerned regulatoryauthority.

iii. The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board 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 todemonstrate the similar efficacy and safety to innovator product covering following requirements:

a. The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).
b. The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.
c. The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.
d. The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.
e. The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.

iv. The firm shall provide the lot release certificate of the finished product manufacturedby same bulk concentrate/ ready to fill from country of export (If applicable).

v. The firm shall provide the 6 months accelerated and real time stability studies for drug substance.

vi. The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in USP monograph of Enoxaparin Sodium in comparison with Innovator product.

vii. The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all

the batches along with all the tests as detailed in USP monograph of Enoxaparin Sodium Injection. All these tests shall be performed in comparison with innovator product.

viii. The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used:
   a. SDS-PAGE for individual proteins
   b. GC-MS for lipid impurities
   c. Threshold ® Total DNA Assay System for DNA content.

ix. 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 systemsused to manufacture, etc. the firm shall inform DRAP immediately along with relevantdocuments.

x. 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.

xi. 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.

xii. If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.

xiii. All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.

xiv. For the already registered and approved drugs for local manufacturing the current guidelines shall apply**.**

ii) For Finished Import:

1. The physical and chemical characteristics of enoxaparin.
2. The nature of the heparin material and the chemical process used to break up heparin chains into smaller pieces.
3. The nature and arrangement of components that constitute enoxaparin.
4. Certain laboratory measurements of the product's anticoagulant activity
5. Certain aspects of the drug's effect in humans.

The following checklist will be used for Imported Enoxaparins:

Sr. No.	Required Documents	Documents Provided by the Firm	Remarks
1.	Equivalence of physicochemical properties, such as:		
	a. Molecular weight distribution using size exclusion chromatography		
	b. Chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).		
2.	Equivalence of heparin source material (i.e. heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline		

	b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.		
3.	Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by following: a. Capillary Electrophoresis (CE) b. Reverse phase high-performance liquid chromatography (RP-HPLC) c. Strong anion exchange HPLC (SAX-HPLC) d. Mass spectroscopy e. Nuclear magnetic resonance (NMR) spectroscopy. f. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.		
4.	Equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.		
5.	Equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.		

Moreover, Division of Biological Evaluation & Research is of the opinion that before implementation of these guidelines, the input of all the local manufacturers of Biological Drugs may be taken.

A policy may be decided by Registration Board regarding the implementation of above guidelines for already approved and registered Enoxaparin products.

Discussion:

Division of Biological Evaluation & Research apprised the Board that they are of the opinion that before implementation of these guidelines, the input of all the local manufacturers of Biological Drugs may be taken. However, Registration Board asked representatives of Pharma Bureau and PPMA and they agreed with the guidelines.

Decision: Keeping in view the recommendations of Committee on Biological Drugs, Registration Board decided to adopt the following guidelines as regulatory requirements for registration of Enoxaparin Injections.

1. For Bulk Concentrate Import, Local Formulation and Filling:

i. The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide bulk concentrate 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 oforigin.

ii. 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 bulk concentrate after submission of data to the concerned regulatory authority.

iii. The firms shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (bulk concentrate) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board todemonstrate the similar efficacy and safety to innovator product covering following requirements:

a. The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).
b. The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.
c. The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.
d. The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.
e. The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.

iv. The firm shall provide the lot release certificate of the finished product manufacturedby same bulk concentrate/ ready to fill from country of export (If applicable).

v. The firm shall provide the 6 months accelerated and real time stability studies for drug substance.

vi. The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk concentrate as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.

vii. The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all

the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.

viii. The local manufacturer shall perform suitable tests to evaluate the product and process related impurities both in their product and in Innovator product e.g. Total proteins, Individual proteins, Lipids and DNA content etc. The following techniques may be used:
   a. SDS-PAGE for individual proteins
   b. GC-MS for lipid impurities
   c. Threshold ® Total DNA Assay System for DNA content.

ix. 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 relevantdocuments.

x. 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.

xi. 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.

xii. If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.

xiii. All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.

xiv. If an applicant does not have the requisite testing facility to perform above tests, they can outsource the required tests to a certified laboratory.

xv. For the already registered drugs, the current guidelines shall apply at the time of renewal.

2. For Ready to Fill Bulk Import, Local Filling:

i. The firms shall provide legalized GMP certificate of biological drug substance manufacturer abroad (who will provide 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 oforigin.

ii. 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 ready to fill bulk after submission of data to the concerned regulatory authority.

iii. The firm shall provide the complete data as adopted for imported Enoxaparin injections in 281st meeting of Registration Board of the finished product of same source (ready to fill bulk) manufactured either from country of origin or by any reference regulatory authority as adopted by Registration Board todemonstrate the similar efficacy and safety to innovator product covering following requirements:
   a. The first criterion for demonstrating sameness of enoxaparin is equivalence of physicochemical properties, such as molecular weight distribution using size exclusion chromatography, chain mapping by cetyltrimethylammonium-coated strong

anion exchange chromatography, matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).

b. The second criterion for demonstrating the sameness of enoxaparin is equivalence of heparin source material (ie, heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (ie, cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.

c. The third criterion for demonstrating the sameness of enoxaparin is equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by capillary electrophoresis (CE), reverse phase high-performance liquid chromatography (RP-HPLC), strong anion exchange HPLC (SAX-HPLC), mass spectroscopy, and nuclear magnetic resonance (NMR) spectroscopy. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.

d. The fourth criterion for establishing sameness of enoxaparin is equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.

e. The fifth criterion for establishing sameness of enoxaparin is equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.

iv. The firm shall provide the lot release certificate of the finished product manufacturedby same bulk concentrate/ ready to fill from country of export (If applicable).

v. The firm shall provide the 6 months accelerated and real time stability studies for drug substance.

vi. The local manufacturer shall perform all the tests on Enoxaparin Sodium bulk as detailed in Pharmacopoeial monograph of Enoxaparin Sodium.

vii. The local manufacturer shall manufacture three trial batches of the finished biological product to finalize the formulation and then perform the six months stability data on all the batches along with all the tests as detailed in Pharmacopoeial monograph of Enoxaparin Sodium Injection.

viii. 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 relevantdocuments.

ix. 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.

x. 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.

xi. If any of the conditions is not fulfilled or public health risk reported at any stage, the drug registration shall stand cancelled with immediate effect.

All the provisions as contained in the Drugs Act, 1976 and rules made there under including provisions of Lot Release certification from National Control Laboratory for Biologicals shall be strictly adhered to.

xii. If an applicant does not have the requisite testing facility to perform above tests, they can outsource the required tests to a certified laboratory.

xiii. For the already registered drugs, the current guidelines shall apply at the time of renewal.

iii) For Finished Import:

The importer shall provide the following documents as already approved in 281st meeting of Registration Board.

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

v. Certain aspects of the drug's effect in humans.

vi. For the already registered drugs, the current guidelines shall apply at the time of renewal.

The documents will be evaluated as per following checklist:

Sr. No.	Required Documents	Documents Provided by the Firm	Remarks
1.	Equivalence of physicochemical properties, such as:		
	a. Molecular weight distribution using size exclusion chromatography		
	b. Chain mapping by cetyltrimethylammonium-coated strong anion exchange chromatography matrix-assisted laser desorption ionization mass spectrometry (MALDIMS), gel permeation chromatograph—electro spray ionization mass spectroscopy (GPC-ESI-MS), or reverse phase ion pair—electro spray ionization mass spectroscopy (RPIPESI-MS).		
2.	Equivalence of heparin source material (i.e. heparin that is derived from porcine intestinal mucosa and that meets USP monograph standards for heparin sodium USP) and mode of depolymerization (i.e. cleavage by alkaline b-elimination of the benzyl ester derivative of heparin). The equivalent heparin source material should have at least a similar distribution of natural disaccharide building block sequences (within the context of itsvariability). If an equivalent mode of depolymerization is used, the generic drug products should be at least similar.		
3.	Equivalence in disaccharide building blocks, fragment mapping, and sequence of oligosaccharide species. This can be achieved by exhaustive digestion of enoxaparin with purified heparin digesting enzymes (heparinases I, II, and III) and nitrous acid, among other means, to yield the constituent disaccharide		

	building blocks comprising enoxaparin. These individual disaccharide building blocks can be quantified by following: a. Capillary Electrophoresis (CE) b. Reverse phase high-performance liquid chromatography (RP-HPLC) c. Strong anion exchange HPLC (SAX-HPLC) d. Mass spectroscopy e. Nuclear magnetic resonance (NMR) spectroscopy. f. Chemical approaches such as analysis with modifying reagents (e.g. sodium borohydride, nitrous acid) or modifying enzymes (eg, 2-0-sulfatase, 6-0-sulfatase, and 5-glucuronidase) can be included.		
4.	Equivalence of in vitro biological and biochemical assay results using activated partial thromboplastin time (aPTT) and Heptest prolongation time. The equivalence in anti-Xa activity, anti-IIa activity, and anti-Xa/anti-IIa ratio between the generic LMWHs should be provided.		
5.	Equivalence of ex vivo pharmacodynamic (PD) profile in human volunteers. The comparison of in vivo PD profiles is based on measurements of in vivo anti-Xa and anti-IIa profiles.		

B. Pharmaceutiacl Evaluation & Registration Division:

- **Pharmaceutiacl Evaluation Cell:**

Case No. 01: Registration Applications of Drugs for Which Stability Study Data is Submitted.

a. Verification of Stability Study Data.

Evaluator PEC-IV

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
1866	M/s. Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar.	Empaa-M XR 12.5 mg/1000mg Tablet Each film coated Extended Release tablet contains Empagliflozin…..12.5mg Metformin Hydrochloride…….1000mg Sodium Glucose Co transporter 2 Inhibitors, Biguanides (Manufacturers specifications)	Form-5D Dy.No.4875; 04-02-2019; Rs.50,000/- 04-02-2019 As per SRO As per SRO	Synjardy Xr tablet of USFDA approved Last inspection conducted on 15-09-2017 and report concludes that Overall the firm was GMP Compliant	

STABILITY STUDY DATA

Drug	Empaa-M XR 12.5 mg/1000mg Tablet			
Name of Manufacturer	M/s. Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar.			
Manufacturer of API	Empagliflozin	M/s Zhejiang Hongyuan Pharmaceuticals co ., Ltd		
	Metformin Hydrochloride	M/s IOL Chemicals and Pharmaceuticals		
API Lot No.	Empagliflozin	20180515		
	Metformin Hydrochloride	4250/1203/18/A-0184PM		
Description of Pack (Container closure system)	Alu Blister			
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C / 75% ± 5% RH			
Time Period	Real time: 6 months Accelerated: 6 months			
Frequency	Accelerated: 0,1,2 3,4,6 (month) Real Time: 0,3 ,6 (month)			
Batch No.	T- 28	T- 29	T- 30	
Batch Size	1200 Tablet	1200 Tablet	1200 Tablet	
Manufacturing Date	10-08-2018	10-08-2018	10-08-2018	
Date of Initiation	12-08- 2018	12-08- 2018	12-08- 2018	

No. of Batches	3		
Date of Submission	04-02-2019 (Dy. No. 4875)		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
Sr.	**Documents To Be Provided**	**Status**	
1.	COA of API	Empagliflozin	Copy of COA by M/s Zhejiang Hongyuan Pharmaceuticals co ., Ltd Limited is submitted.
		Metformin Hydrochloride	Copy of COA by M/s IOL Chemicals and Pharmaceuticals Limited 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.	Empagliflozin	Copy of GMP Certificate No. ZJ20180032 by China Food and Drug Adminstration valid till 03-14-2023.
		Metformin Hydrochloride	Copy of GMP Certificate No. Drugs (7) Pb.2018/ 1895 by Food & Drug Administration Punjab valid till 07-03-2020.
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.	Empagliflozin	Copy of Commercial Invoice No 10053012 Dated: 11-07-2018 is submitted attested by ADC(Peshawar) dated ;19-07-2018.
		Metformin Hydrochloride	Copy of Commercial Invoice No TM/104/18-19 Dated: 17-01-2018 is submitted. But not ADC 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

- The panel may be requested to verify and report about following points in addition to authenticity of stability data and associated documents,

. Import of API because Form 3 ,form 7 and goods declaration for metformin attached but commercial invoice not ADC attested.

. Applied technology of Active coating for Empagliflozin in which drug is loaded via coating solution on the core tablet of metformin hydrochloride.

. Justification of 5% overage of Empagliflozin in master formulation (which is required to be based on study/scientific rationale) for which firm has stated that Empagliflozin overage was inducted due to drug loss during spray coating process and to attain the satisfactory contents of Empagliflozin as per claim.

. Method development study to justify that the result of dissolution analysis for metformin as performed by UV method have not been interfered with the ingredients of formulation specially the other API i.e Empagliflozin present in the same sample aliquote.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of **Empaa-M XR**

12.5/1000mg Tablets by **M/s Weatherfolds Pharmaceuticals, Plot No. 69 Phase II, Industrial Estate, Hattar**.

Inspection of the firm M/s Weatherfolds Pharmaceuticals, Plot No. 69 Phase II, Industrial Estate, Hattar is conducted today on 10.05.2019 in compliance to PEC letter No. F.13-11/2017-PEC (Vol-I) dated 25.04.2019 for the verification o authenticity of stability data for the registration of following products.
Empaa-M XR 12.5/1000mg Tablets
Empaa 25 mg Tablet

The following panel conducted inspection of the firm

- **Prof. Dr. Jamshed Ali Khan, Member, CLB**
- **Dr. Muhammad Khalid Javed, Director, DTL , Peshawar**
- **Ch. Zeeshan Nazir, Deputy Director (QA), DRAP, Islamaba**d

The panel go through the record of the raw material of Metformin Hcl. The firm's representative provided the In-gate pass, Good Receiving Note, Goods Declaration, Commercial Invoice, Form-3, Form-7 and testing record of the imported raw material. However the firm fails to provide the attested invoice by the Assistant Director (I &E). Provided record shows that the firm imported Metformin Hcl from the firm M/s The Moleculez, Mumbai, India.

The firm is using manual coating technique for the coating of Empagliflozin on the core of Metformin Hcl. The firm uses 5 kg coating pan for the R&D purpose. The record of testing of the finish product is scrutinized and found satisfactory.

Technical staff provided testing record of the finish product. The technical staff stated that the coating of Empagliflozin was done with 100 %, 102 %, 105 % and 110 %. The testing record show that 105 % of Empagliflozin provided 100 % results on finish testing. The firm after trial decided to use overage of 5 % of Empagliflozin.

Technical staff stated that during test trial of finish product, they have developed a placebo for the adjustment of excipients as well as Empa. The UV method does not interfere with ingredients of formulation and Empagliflozin.

Stability data of the above mentioned products is also verified through manual record and directory of HPLC. The HPLC provided is 21 CFR compliant, Water's 600 pump, 486 Detector with Empower software. Manual record of above mentioned products is also verified and found satisfactory.

Keeping in view the above mentioned facts, the panel unanimously verified the authenticity of stability data of below mentioned products.

Empaa-M XR 12.5/1000mg Tablets
Empaa 25 mg Tablet

S.No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Import documents including internal record is available. However Goods Declaration and Commercial Invoice of Metformin Hcl is also available.
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	GMP compliant
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	Working standards provided by the manufacture.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	YES
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes
Q.No.6	Do you use API manufacturer method of testing for	Yes

	testing API?	
Q.No.7	Do you have stability studies reports on API?	Yes
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes
Q.No.9	Do you have method for quantifying the impurities in the API?	No
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes only of API
Q.No.11	Have you used pharmaceutical grade excipients?	Yes
Q.No.12	Do you have documents confirming the import of the used excipients?	No
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 applied product?	Yes
Q.No.15	Have you performed Drug-excipients compatibility studies?	Brand Formulation is taken as standard
Q.No.16	Have you performed comparative dissolution studies?	Yes
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 applied product?	No
Q.No.19	Are the equipments in product development section qualified?	N/A
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	N/A
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	N/A
Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	Yes
Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	Yes
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?	Yes
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?	N/A
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?	Yes
Q.No.29	Is your method of analysis stability indicating?	Yes
Q.No.30	Is your HPLC software is 21CFR compliant? (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 shall also be	Yes 21 CFR, Water's 600 pump, 486 Detector with Empower software.

	reported.)	
Q.No.31	Can you show Audit Trail reports on stability studies testing?	Yes
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	Yes
Q.No.33	Do you have stability batches kept on stability testing?	Yes
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	Yes
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported.)	Two stability chambers are provided. Each is having capacity of 600 litres with manual record keeping.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes
Decision: Registration Board decided to approve registration of "Empaa-M XR Tablet (Empagliflozin 12.5mg, Metformin Hydrochloride 1000mg)" with Innovator's specifications by M/s. Weather Folds Pharmaceuticals, Plot # 69, 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.		

Evaluator PEC-XII

Case No. 02: Registration applications of drugs for which stability study data is submitted

- **a.** New cases
- **b.** Deferred cases
- **c.** Verification of stability study data
- **d.** Exemption from onsite verification of stability data

Case No. 02: Registration applications of drugs for which stability study data is submitted

c. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1867	**M/s The Searle Company Limited,** F-319, SITE Karachi.	**Tapendol Tablets 100mg** Each film coated tablet contains: Tapentadol (as hydrochloride) …100mg Analgesic (Other opioids) Manufacturer's Specifications.	Form 5-D Dairy No. 35710 dated 29-10-2018. Rs.50,000/- dated 29-10-2018. (Challan#0765175) As per SRO	NUCYNTA TABLETS film-coated 100mg by M/s Bristol-Myers Squibb Company (USFDA approved) Last GMP inspection report dated 13-2-2018: Follow up, as per the data provided by QA&LT Division.

STABILITY STUDY DATA	
Drug	Tapendol Tablets 100mg (Tapentadol)
Name of Manufacturer	M/s The Searle Company Limited, F-319, SITE Karachi.
Manufacturer of API	M/s Symed Labs Limited, i. **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India. ii. **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India.

API Lot No.	6TDL0020917		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 75±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	18PD-048	18PD-049	18PD-050
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	Feburary 2018	Feburary 2018	Feburary 2018
Date of Initiation	March 2018	March 2018	March 2018
No. of Batches	03		
Date of Submission	18-12-2018 (Dy. No. 43085)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1)	COA of API	• Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India has been submitted. Batch#2TDL0231115. • Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India. has been submitted. Batch#6TDL0020917. • Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India has been submitted. Batch#2TDL0170417.
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.	Photocopy of GMP Certificate No. L.Dis.No.2824/A3/2018 detailed as under: M/s Symed Labs Limited, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India. issued by Drugs Control Administration, Government of Telangana, India is submitted. Valid till 17-05-2019.
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.	• Firm has submitted following: i. Photocopy of ADC (Karachi) attested Commercial Invoice dated 26-01-2016 containing batch details of Batch No. 2TDL0231115 is submitted. Quantity: 1 kg. ii. Photocopy of ADC (Karachi) attested Commercial Invoice dated 08-11-2017 containing batch details of Batch No. 6TDL0020917 is submitted. Quantity: 2 kg. iii. Photocopy of ADC (Karachi) attested Commercial Invoice dated 18-05-2017 containing batch details of Batch No. 2TDL0170417 is submitted. 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

Evaluation by PEC:

- Manufacturer of API i.e. M/s Symed Labs Limited, India, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India could not be confirmed from List of Manufacturing Units in Telangana listed on the website. However, firm has submitted copy of GMP certificate issued by Drugs Control Administration, Government of Telangana, India.
- Firm has not submitted GMP certificate of Unit-II of API manufacturer i.e. M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India

Decision:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1868	M/s The Searle Company Limited, F-319, SITE Karachi.	Tapendol Tablets 75mg Each film coated tablet contains: Tapentadol (as hydrochloride) …75mg Analgesic (Other opioids) Manufacturer's Specifications.	Form 5-D Dairy No. 35709 dated 29-10-2018. Rs.50,000/- dated 29-10-2018. (Challan#0765174) As per SRO	NUCYNTA TABLETS film-coated 75mg by M/s Bristol-Myers Squibb Company (USFDA approved) Last GMP inspection report dated 13-2-2018: Follow up, as per the data provided by QALT division.

STABILITY STUDY DATA	
Drug	Tapendol Tablets 75mg (Tapentadol)
Name of Manufacturer	M/s The Searle Company Limited, F-319, SITE Karachi.
Manufacturer of API	M/s Symed Labs Limited,

	iii. **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India. iv. **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India.		
API Lot No.	2TDL0170417		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 75±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6 (Months)		
Batch No.	18PD-056	18PD-064	18PD-065
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	March 2018	March 2018	March 2018
Date of Initiation	March 2018	March 2018	March 2018
No. of Batches	03		
Date of Submission	18-12-2018 (Dy. No. 43085)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	COA of API	• Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India has been submitted. Batch#2TDL0231115. • Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India. has been submitted. Batch#6TDL0020917. • Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India has been submitted. Batch#2TDL0170417.
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.	• Photocopy of GMP Certificate No. L.Dis.No.2824/A3/2018 detailed as under: M/s Symed Labs Limited, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India. issued by Drugs Control Administration, Government of Telangana, India is submitted. Valid till 17-05-2019.
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.	• Firm has submitted following: i. Photocopy of ADC (Karachi) attested Commercial Invoice dated 26-01-2016 containing batch details of Batch No. 2TDL0231115 is submitted. Quantity: 1 kg. ii. Photocopy of ADC (Karachi) attested Commercial Invoice dated 08-11-2017 containing batch details of Batch No. 6TDL0020917 is submitted. Quantity: 2 kg. iii. Photocopy of ADC (Karachi) attested Commercial Invoice dated 18-05-2017 containing batch details of Batch No. 2TDL0170417 is submitted. 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

Evaluation by PEC:

- Manufacturer of API i.e. M/s Symed Labs Limited, India, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India could not be confirmed from List of Manufacturing Units in Telangana listed on the website. However, firm has submitted copy of GMP certificate issued by Drugs Control Administration, Government of Telangana, India.
- Firm has not submitted GMP certificate of Unit-II of API manufacturer i.e. M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India

Decision:

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1869	M/s The Searle Company Limited, F-319, SITE Karachi.	Tapendol Tablets 50mg Each film coated tablet contains: Tapentadol (as hydrochloride) …50mg Analgesic (Other opioids) Manufacturer's Specifications.	Form 5-D Dairy No. 35708 dated 29-10-2018. Rs.50,000/- dated 29-10-2018. (Challan#0765173) As per SRO	NUCYNTA TABLETS film-coated 50mg by M/s Bristol-Myers Squibb Company (USFDA approved) Last GMP inspection report dated 13-2-2018: Follow up, as per the data provided by QALT division.

STABILITY STUDY DATA

Drug	Tapendol Tablets 50mg (Tapentadol)
Name of Manufacturer	M/s The Searle Company Limited, F-319, SITE Karachi.
Manufacturer of API	M/s Symed Labs Limited, v. **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad.,

	India. vi. **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India.		
API Lot No.	2TDL0231115		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Accelerated: 40°C ± 2°C & 75±5%RH Real Time: 30°C ± 2°C & 75±5%RH		
Time Period	Accelerated: 6 months Real Time: 24 months		
Frequency	Accelerated: 0,3,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	16PD-098	16PD-110	16PD-111
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	April 2016	May 2016	May 2016
Date of Initiation	May 2016	May 2016	May 2016
No. of Batches	03		
Date of Submission	18-12-2018 (Dy. No. 43085)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents to Be Provided	Status
1.	COA of API	• Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India has been submitted. Batch#2TDL0231115. • Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India. has been submitted. Batch#6TDL0020917. • Copy of COA for Tapentadol hydrochloride from M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India has been submitted. Batch#2TDL0170417.
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.	• Photocopy of GMP Certificate No. L.Dis.No.2824/A3/2018 detailed as under: M/s Symed Labs Limited, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India. issued by Drugs Control Administration, Government of Telangana, India is submitted. Valid till 17-05-2019.
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.	• Firm has submitted following: i. Photocopy of ADC (Karachi) attested Commercial Invoice dated 26-01-2016 containing batch details of Batch No. 2TDL0231115 is submitted. Quantity: 1 kg. ii. Photocopy of ADC (Karachi) attested Commercial Invoice dated 08-11-2017 containing batch details of Batch No. 6TDL0020917 is submitted. Quantity: 2 kg. iii. Photocopy of ADC (Karachi) attested Commercial Invoice dated 18-05-2017 containing batch details of Batch No. 2TDL0170417 is submitted. 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

Evaluation by PEC:

- Manufacturer of API i.e. M/s Symed Labs Limited, India, **Unit-VI**, situated at Sy.No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India could not be confirmed from List of Manufacturing Units in Telangana listed on the website. However, firm has submitted copy of GMP certificate issued by Drugs Control Administration, Government of Telangana, India.
- Firm has not submitted GMP certificate of Unit-II of API manufacturer i.e. M/s Symed Labs Limited, **Unit-II**,Plot No: 25/B, Phase-III, IDA, Jeedimetla, Hyderabad., India

Decision:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Tapendol (Tapentadol) 50mg, 75mg & 100mg Tablets by M/s The Searle Company Limited, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 23rd January, 2019.
Investigation Date and Time: 11th March, 2019. (Forenoon)
Investigation Site: Factory premises of M/s The Searle Company Limited, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. The Searle Company Limited, Karachi for registration of Tapendol (Tapentadol) 50mg, 75mg & 100mg 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.

1. "Manufacturer of API ie. M/s Symed Labs Limited, India, Unit VI situated at Sy. No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India could not be confirmed from list of manufacturing units in Telangana listed on the website. However, firm has submitted copy of GMP certificate issued by Drugs Control Administration, Government of Telangana, India"
2. "Firm has not submitted GMP certificate of Unit II of API manufacturer i.e. M/s Symed Labs Limited, Unit II Plot No. 25/B, Phase III, IDA Jeedimetla, Hyderabad, India"

Composition of Panel:

1. Dr. Rafeeq Alam, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board.
2. Mr. Aslam Shah, 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:

Q. NO.	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of Tapentadol API including approval from DRAP?	The firm has imported Tapentadol raw material 1.0Kg having lot number 2TDL0231115, 5.0Kg having lot number 2TDL0170417 & 2.0Kg 6TDL0020917 having lot number from M/s SYMED LABS LIMITED, have ADC clearance on 26th Jan-2016, 18th May-2017 and 8th Nov 2017 respectively and got approval from DRAP Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm has implemented proper vendor evaluation system. The rationale for the selection of this manufacturer was availability of GMP certificate from relevant authority, availability of DMF, working standard, stability studies of API.
3. .	Do you have documents confirming the import of Tapentadol reference standard and impurity standards?	The firm has imported working standard along with API consignment.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, and working standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of API manufacturer issued by Drug control administration government of Telangana for both units II & VI.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer's method of analysis for API testing.
7.	Do you have stability studies reports on APIs?	The firm has long term and accelerated study reports for Tapentadol provided by M/s SYMED LABS LIMITED.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing is as per SIM as Impurity profile has been reported in stability study report of Tapentadol provided by M/S SYMED LABS LIMITED
9.	Do you have method for quantifying the impurities in the API?	The firm had API manufacturer method for quantification of impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has following remaining quantities of API' are;
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients i.e. Microcrystalline cellulose, Lactose monohydrate, povidone, Croscarmellose sodium & Magnesium stearate.
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 necessary test reports and other record for the excipients used.

Lot No	Qty Received	Qty Remaining
2TDL0231115	1.0 Kg	0.0 g
2TDL0170417	5.0Kg	3.45Kg
6TDL0020917	2.0Kg	0.128Kg

14.	Do you have written and authorized protocols for the development of Tapentadol Tablets Range?	The firm has written and authorized protocols for the development of Tapentadol Tablets 50mg, 75mg & 100mg.
15.	Have you performed Drug-excipient compatibility studies?	The firm has used same excipient as used by the innovator, therefore, compatibility studies were not performed.
16.	Have you performed comparative dissolution studies?	The firm has not performed comparative dissolution profile due to non-availability of reference product, 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 product development (R&D) section with requisite manufacturing and analysis facilities.
18.	Do you have necessary equipment available in product development section for development of Tapentadol Tablets Range?	The firm has necessary equipment available in product development section for development of the Tapentadol tablets.
19.	Are the equipment in product development section qualified?	The 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 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?	The firm had qualified staff comprising of 24 members in R&D department.
22.	Have you manufactured three stability batches for the stability studies of Tapentadol Tablets Range required?	The firm has manufactured three stability batches for stability studies for each strength; 1. Tapentadol Tablets 100mg Batch numbers are 18PD-048, 18PD-049 & 18PD-050 having batch size 1500 tablets each. 2. Tapentadol Tablets 75mg Batch numbers are 18PD-056, 18PD-064 & 18PD-065 having batch size 1500 tablets each. 3. Tapentadol Tablets 50mg Batch numbers are 16PD-098, 16PD-110 & 16PD-111 having batch size 1500 tablets each.
23.	Do you have any criteria for fixing the batch size of stability batches?	The firm had informed that their criteria for fixing batch size is based on number of samples required for stability studies for all 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 the method of testing for finished product.
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 Tapentadol Tablets Range and the	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Tapentadol Tablets 50mg, 75mg & 100mg tablets.

	finished drug?	
29.	Do your method of analysis stability indicating?	The firm used stability indicating method for the quantification of any impurities and degradation products in the tablets kept on stability testing.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm. The firm has Water's Alliance 2695 with Empower 3 software.
31.	Can you show Audit trail reports on Tapentadol Tablets Range testing?	Audit trail on the testing reports is available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches only.
33.	Do you have stability batches kept on stability testing?	The firm has completed accelerated stability testing on three stability batches of each strength. Currently 9th month real time stability testing has been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in Tapentadol Tablets Range production and analysis?	The firm has valid calibration status for the equipment used in Tapentadol Tablet Range for production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Firm has software for monitoring of stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities were GMP compliant.
37.	Any Other query raised by PER Division: 1. "Manufacturer of API ie. M/s Symed Labs Limited, India, Unit VI situated at Sy. No.744, 745, 750, 751, 752 & 753, Mandollagudem Village, Choutuppal Mandal, Yadadri District, Telangana, India could not be confirmed from list of manufacturing units in Telangana listed on the website. However, firm has submitted copy of GMP certificate issued by Drugs Control Administration, Government of Telangana, India" 2. "Firm has not submitted GMP certificate of Unit II of API manufacturer i.e. M/s Symed Labs Limited, Unit II Plot No. 25/B, Phase III, IDA Jeedimetla, Hyderabad, India"	1. As per record available with the firm, Unit-VI is a GMP certified manufacturing unit as evident from GMP certificate provided by the firm, however, the address of the Unit VI of the manufacturer is mentioned at the corporate website of M/s Symed Labs Limited. 2. The firm has GMP certificated issued by Drug Control Administration, Govt of Telangana hereby annexed at Annex-I

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Tapendol 50mg, 75mg & 100mg Tablets (Tapentadol) is verifiable to satisfactory level.
2. The related manufacturing area, equipments, personnel and utilities are compliant and are suited for the manufacturing of Tapendol 50mg, 75mg & 100mg Tablets.

Recommendations:

The firm may kindly be granted necessary registration of Tapendol 50mg, 75mg & 100mg tablets.

Decision: Registration Board decided to approve registration of "Tapendol Tablets 50mg, Tapendol Tablets 75mg &Tapendol Tablets 100mg" by M/s. The Searle Company Limited, Karachi. Manufacturer will place first three production batches of the products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case No. 06 Cases for Correction In The Decision Of Board Meeting:

Following two cases of Resto Tablets 49/51mg & Resto Tablets 97/103mg of Ms Werrick were presented before the Board in its 287th Meeting. Inadvetently decision of one strength was mentioned against other & vice versa.

Now these two cases are again placed before the board for correction of decision.

1.	Name and address of manufacturer / Applicant	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Resto Tablets 49/51mg
	Composition	Each film coated tablet contains: Sacubitril……..49mg Valsartan……..51mg
	Diary No. Date of R& I & fee	Dy No.29045; 30-08-2018: 20,000/- ; 06-08-18
	Pharmacological Group	Neprilysin Inhibitor, Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 60's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (Entresto Tablet of Novartis pharms)
	Me-too status	Savel Tablets 24/26mg of PharmaEvo
	GMP status	GMP Inspection conducted on 07-12-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA			
Drug	Resto Tablets 49/51mg		
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China		
API Lot No.	Lot #: 20170203 , Quantity; 3kg		
Description of Pack (Container closure system)	Alu /PVC Blister Pack in Unit carton		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Trial #01	Trial #02	Trial #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2017	10-2017	10-2017
Date of Initiation	05-01-2018	05-01-2018	05-01-2018
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.	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, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice dated 14-06-2017 attested by ADC, 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 firm has submitted 26 Weeks Accelerated and 26 Weeks Real Time Stability Data for 03 Batches.
- As per submitted stability study data, only one injection of Standard solution for both Assay test and Dissolution test has been recorded. Clarification is required.

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: 06-07-2018 vide diary no. 23459

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th & finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed. • The firm has 21CFR compliant HPLC software • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice dated 19th of May 2017 declaring 3kgs quantity of API Sacubitril + Valsartan (1:1) has been submitted which is not attested by ADC, DRAP Islamabad. **Copy of commercial invoice is not attested by ADC, DRAP Islamabad.**
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard & impurity Standards: **For working standard:** Sacubitril sodium: 99.4 % Valsartan: 100% **For Impurity standard:** Valsartan Related compound C: 92 % Valsartan Related compound B: 99.5 % **COA for the working standard Sofosbuvir is not submitted.**
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 declaring following information: **Certificate No**.GD20170777 **Issued to**: M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China. **Issued by**:Zhuhai Food & Drug Administration, Guangdong

<table>
<tr><td></td><td></td><td>Province, China.
Validity: Valid Till 24-12-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Applicant has submitted following COAs:
Copy of COA of API (Batch # 20170203) from M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China has been submitted.
Copy of COA of reference standard has been submitted
Copy of COA of Velpatasvir impurity Standards B & C has been submitted
COAs of Sofosbuvir impurity standards has not 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 all the excipients used in the formulation of applied product.
Commercial invoice dated 14-01-17 for Talcum.
Commercial invoice dated 17-11-16 for HPMC.
Commercial invoice dated 25-09-16 for Aerosil.
Commercial invoice dated 03-11-16 for Magnesium stearate.
Commercial invoice dated 01-11-17 for microcrystalline cellulose 200.
Commercial invoice dated 25-04-17 for cross carmilose.(but you have used cross carmilose sodium)
Commercial invoice dated 25-09-17 for titanium dioxide.(but you have used cross carmilose sodium)
Commercial invoice dated 07-12-17 for Color Red # 40 (Lake)</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 Resto Tablets 49/51mg”.</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>10-2017</td></tr><tr><td>Trial # 02</td><td>1500 tablets</td><td>10-2017</td></tr><tr><td>Trial # 03</td><td>1500 tablets</td><td>10-2017</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>1203 Tab
(60 packs * 20’s)</td><td>300
(15 packs * 20’s)</td><td>900
(45 packs * 20’s)</td></tr><tr><td>Trial # 02</td><td>1214 Tab
(60 packs * 20’s)</td><td>260
(13 packs * 20’s)</td><td>940
(47 packs * 20’s)</td></tr><tr><td>Trial # 03</td><td>1219
(60 packs * 20’s)</td><td>260
(13 packs * 20’s)</td><td>940
(47 packs * 20’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</td><td>Firm has submitted photocopies of data logger record for chambers</td></tr>
</table>

	temperature and humidity monitoring of stability chambers (real time and accelerated).	used in Real Time & Accelerated stability studies of applied product from 01-01-2018 to 15-09-2018.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: • Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house). • COAs for Sacubitril/Valsartan Complex (Supplier/Manufacturer).
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 photocopies of following: • FPP Test/Analysis Method & FPP Specifications (In-house) for Resto 49/51mg tablet.
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 according to zone VIb conditions.
16.	Analysis reports for excipients used.	The firm has submitted copy 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 49/51mg manufactured by M/S. Novartis Europharn Limited with Batch No.TK538. 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 15-08-2017 to 19-02-2018 was submitted by the firm.

Remarks:

Queries	Response by the firm
1. Evidence for procurement of working standards and impurity standards is not submitted.	We received working standard & impurity standards along with API. So there is no separate invoice
2. COAs of Sacubitril impurity standards has not been submitted.	There is no specific impurity of Sacubitril as mentioned in the COA of API. The COA mentions specific impurity for valsartan only.
3. Copy of commercial invoice confirming the import of API is not ADC attested. Clarify.	Applicant has submitted ADC attested Clearance Certificate dated 07-06-17 for the import of 03 kgs Sacubitril+ Valsartan.
4. Evidence of purchase of reference drug product against which the CDP is carried out is not submitted.	The applicant has submitted the photocopy of outer carton of Entresto 97/103mg tablets.
5. You have mentioned two types of primary packaging materials (Alu/alu & Alu/PVC) on stability study data sheets. Mention that one packaging material which is used during stability studies of applied formulations.	The applicant has confirmed Alu/PVC as a primary packaging material for applied formulation.
6. Stability protocols, Analytical method for API & FPP & Analytical method validation protocols are not attested.	Firm has submitted the Stability protocols, Analytical method for API & FPP & Analytical method
7. Which analytical method is used by the firm for test/analysis of applied formulation either Supplier or In-house,	The applicant has in-house analytical method for applied formulation.

clarify.	
8. Analytical report for Color Red # 40 (Lake) is not submitted.	Firm has submitted Colour RED # 40 Lake packaging material for applied formulation.
9. Batch release test/analysis results of applied drug product are not submitted.	
10. Assay of Valsartan & Sacubitril (APIs) has to be calculated by these formulas (Area of sample/Area of standard × Conc. of standard/Conc. of sample × 100) & (Area of sample/Area of standard × Conc. of standard/Conc. of sample× 0.949 × 100) respectively as per submitted analytical method for test/analysis of API. However the formula used for the calculation of assay results of above stated APIs, as evident by your submitted raw data sheets of stability studies is different. Clarify/ Justify	In the calculation of API, the factor 0.949 is used to calculate the secubitril base (as it is used in the form of secubitril sodium salt) while in the product's stability studies it has already been adjusted in the formulation, so this factor is not required in the assay of stability studies.
11. Assay & Dissolution results of Valsartan & Sacubitril (APIs) are calculated by these formulas (Area of sample/Area of standard × 100) & (Area of sample/Area of standard × 100) respectively as per submitted analytical method for test/analysis of finished product, without considering the concentration & potencies of standards. Clarify/Justify	The potency of Sacubitril is adjusted in weight taken for reference standard whereas valsartan is calculated by its potency formula for assay as mentioned in raw data sheets. In case of dissolution the potency of both valsartan & secubitril is adjusted in weight taken for reference standard.
12. Drug-excipients compatibility studies are not submitted.	Stability Studies (accelerated & real time) are indicative of chemical & physical compatibility with the drug product. These studies clearly demonstrate that the excipients used for the manufacture of the dosage form are compatible with the API.
13. Submit procedure adopted by firm for conduction of CDP.	The firm has submitted procedure for adopted by firm for conduction of CDP.
14. Sacubitril/valsartan (88%) is written in master formulation. What does this 88% mean?	The activity of API is 88% which was adjusted to 100% in the formula.
15. Date acquired 31-01-2018 on the chromatograms for run of dissolution reference in initial studies of trial # 2 of Wertril tablet 49/51 is not verifiable from the submitted audit trail reports. Clarify/Justify.	-------
16. Date acquired 05-05-2018 on the chromatograms for run of dissolution reference in 3rd month studies of trial # 2 of Wertril tablet 49/51 is not verifiable from submitted audit trail reports. Clarify/ Justify.	-------

Decision of 287th meeting:

Registration Board decided to approve registration of "Resto Tablets 49/51mg" by "M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad." 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.

Decision: Registration Board deferred case for confirmation of audit trail of HPLC analysis for stability studies of three trial batches of Resto Tablets 49/51 by Panel already constituted by Chairman, Registration Board.

2.	Name and address of manufacturer / Applicant	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Resto Tablets 97/103mg
	Composition	Each film coated tablet contains: Sacubitril……..97mg Valsartan……103mg
	Diary No. Date of R& I & fee	Dy No.31946; 25-09-2018: 20,000/- ; 06-08-18
	Pharmacological Group	Angiotensin II receptor blocker
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 60's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (Entresto Tablet of Novartis pharms)
	Me-too status	
	GMP status	GMP Inspection conducted on 07-12-2017 with a conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Resto Tablets 97/103mg		
Name of Manufacturer	M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China		
API Lot No.	Lot #: 20170203 , Quantity; 3kg		
Description of Pack (Container closure system)	Alu /PVC Blister Pack in Unit carton		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 26 (weeks) Real Time: 26 (weeks)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Trial #01	Trial #02	Trial #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2017	10-2017	10-2017
Date of Initiation	21-08-2017	21-08-2017	21-08-2017
No. of Batches	03		
Date of Submission	31947 (25-09-2018)		

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.	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	Yes

	chromatograms, laboratory reports, data sheets etc.	
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice dated 14-06-2017 attested by ADC, 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 firm has submitted 26 Weeks Accelerated and 26 Weeks Real Time Stability Data for 03 Batches.
- As per submitted stability study data, only one injection of Standard solution for both Assay test and Dissolution test has been recorded. Clarification is required.

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: 06-07-2018 vide diary no. 23459

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Cell-Tab 400mg (Sofosbuvir) Tablets", which was presented Initially in 256th subsequently in 269th & finally in 276th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Werrick Pharmaceuticals. According to the report following points were confirmed. • The firm has 21CFR compliant HPLC software • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice dated 19th of May 2017 declaring 3kgs quantity of API Sacubitril + Valsartan (1:1) has been submitted which is not attested by ADC, DRAP Islamabad. **Copy of commercial invoice is not attested by ADC, DRAP Islamabad.**
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard & impurity Standards: **For working standard:** Sacubitril sodium: 99.4 % Valsartan: 100% **For Impurity standard:** Valsartan Related compound C: 92 % Valsartan Related compound B: 99.5 % **COA for the working standard Sofosbuvir is not submitted.**
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 declaring following information: **Certificate No**.GD20170777 **Issued to**: M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China.

<table>
<tr><td></td><td></td><td>Issued by:Zhuhai Food & Drug Administration, Guangdong Province, China.
Validity: Valid Till 24-12-2022.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for Evaluation of Vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Applicant has submitted following COAs:
Copy of COA of API (Batch # 20170203) from M/s Zhuhai Rundu Pharmaceutical Co., Ltd, China has been submitted.
Copy of COA of reference standard has been submitted
Copy of COA of Velpatasvir impurity Standards B & C has been submitted
COAs of Sofosbuvir impurity standards has not 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 all the excipients used in the formulation of applied product.
Commercial invoice dated 14-01-17 for Talcum.
Commercial invoice dated 17-11-16 for HPMC.
Commercial invoice dated 25-09-16 for Aerosil.
Commercial invoice dated 03-11-16 for Magnesium stearate.
Commercial invoice dated 01-11-17 for microcrystalline cellulose 200.
Commercial invoice dated 25-04-17 for cross carmilose.(but you have used cross carmilose sodium)
Commercial invoice dated 25-09-17 for titanium dioxide.(but you have used cross carmilose sodium)
Commercial invoice dated 07-12-17 for Color Red # 40 (Lake)</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 Resto Tablets 97/103mg”.</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>10-2017</td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>10-2017</td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>10-2017</td></tr>
</table></td></tr>
</table>

11.	Record of remaining quantities of stability batches.	<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>1112 (55 packs * 20's)</td><td>300 (15 packs * 20's)</td><td>800 (40 packs * 20's)</td></tr><tr><td>Trial # 02</td><td>1130 (55 packs * 20's)</td><td>260 (13 packs * 20's)</td><td>860 (43 packs * 20's)</td></tr><tr><td>Trial # 03</td><td>1117 (55 packs * 20's)</td><td>260 (13 packs * 20's)</td><td>860 (42 packs * 20's)</td></tr></table>
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 chambers used in Real Time & Accelerated stability studies of applied product from 01-01-2018 to 15-09-2018.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopies of following: • Raw Material Test/Analysis Procedures & Raw Material Specifications (In-house). • COAs for Sacubitril/Valsartan Complex (Supplier/Manufacturer).
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 photocopies of following: • FPP Test/Analysis Method & FPP Specifications (In-house) for Resto 97/103mg tablet.
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 according to zone VIb conditions.
16.	Analysis reports for excipients used.	The firm has submitted copy 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 49/51mg manufactured by M/S. Novartis Europharn Limited with Batch No.TK538. 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 15-08-2017 to 19-02-2018 was submitted by the firm.

Remarks:

Queries	Reply by the firm
1. Evidence for procurement of working standards and impurity standards is not submitted.	We received working standard & impurity standards along with API. So there is no separate invoice
2. COAs of Sacubitril impurity standards has not been submitted.	There is no specific impurity of Sacubitril as mentioned in the COA of API. The COA mentions specific impurity for valsartan only.
3. Copy of commercial invoice confirming the	Applicant has submitted ADC attested

import of API is not ADC attested. Clarify.	Clearance Certificate dated 07-06-17 for the import of 03 kgs Sacubitril+ Valsartan.
4. Digital data logger record for Accelerated stability studies from 27-01-2018 to 31-01-2018 is not submitted.	It is submitted now.
5. Evidence of purchase of reference product against which the CDP is carried out is not submitted.	The applicant has submitted the photocopy of outer carton of Entresto 97/103mg tablets.
6. Clarification regarding difference in Manufacturing method submitted in dossier (direct compression) & submitted with Stability studies in Batch Manufacturing Records (Dry granulation consisting of Slugging, Lubrication, Film coating) is required.	Clarified by the applicant.
7. You have mentioned two types of primary packaging materials (Alu/alu & Alu/PVC) on stability study data sheets. Mention that one packaging material which is used during stability studies of applied formulations.	The applicant has confirmed Alu/PVC as a primary packaging material for applied formulation.
8. Justify how assay and dissolution results are calculated by this formula (Area of sample/Area of standard ×100) without considering the potency of working standards. However in supplier analytical method of API, assay is calculated by considering the potency of standard.	The potency of Sacubitril is adjusted in weight taken for reference standard whereas valsartan is calculated by its potency formula for assay as mentioned in raw data sheets. In case of dissolution the potency of both valsartan & secubitril is adjusted in weight taken for reference standard.
9. Stability protocols, Analytical method for API & FPP & Analytical method validation protocols are not attested.	Firm has submitted the Stability protocols, Analytical method for API & FPP & Analytical method validation protocols for applied formulation..
10. Which analytical method is used by the firm for test/analysis of applied formulation either Supplier or In-house, clarify.	The applicant has in-house analytical method for applied formulation.
11. Analytical report for Color Red # 40 (Lake) is not submitted.	It is submitted now.

Decision of 287th RB meeting:

Registration Board decided to defer the case for confirmation of audit trail of HPLC analysis For stability studies of all three trial batches of applied product i.e. Resto Tablets 49/51, by Area FID.

Decision: Registration Board decided to approve registration of "Resto Tablets 97/103mg" by "M/s Werrick pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad." 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.

A. Cases Discussed in 05th meeting of Expert Working Group on Veterinary Drugs

a. VETERINARY BIOLOGICALS LOCALLY MANUFACTURED IN PAKISTAN.

Sr. No.	Name and address of product manufacturer (Applicant)	M/s. Ottoman Pharma 10 Km, Raiwind Road, Lahore.
1.	Brand Name +Dosage Form + Strength	OTTO FLU PLUS + VAC Injectable Emulsion (For Veterinary use only) Each dose contains:- Inactivated AIV H7N3 [Not less than EID_{50} 10^9/ml……....0.06ml Inactivated AIV H5N1 [Not less than EID_{50} 10^9/ml……..….0.06ml
	Type of Form, Diary No. Date of R& I & fee	Form-5, Dy. No.7460(R&I) Date:27-02-2018 Rs.20,000/-.
	Composition	Quantity in 0.3ml Vaccine dose: Inactivated AIV H7N3 [Not less than EID_{50} 10^9/ml (**Active Substance**)……0.06ml Inactivated AIV H5N1 [Not less than EID50 10^9/ml (**Active Substance**)…….……0.06ml Thiomersal (**Preservative**)……0.0005ml Mineral Oil (Montanide oil) (**Excipient**)……...0.18ml
	Pharmacological Group	Biological (Vaccine for veterinary / poultry use only)
	Finished Product Specification	As per Innovators spec.
	Shelf Life	12 Months at 2-8^{0}C
	Document Details	i. Application on form 5 ii. Copy of DML No. 000502, Date of issue 05-08-2017 iii. Fee ChallanRs. 20,000/- iv. Panel inspection for renewal of DML dated 19-12-2017 wherein the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	International Availability	N/A
	Products already registered in Pakistan	i. Bio-Avian ii. GPVAC Flu 5+7
	Previous Decision:	Registration Board referred the case regarding the use of H5N1 strain in Pakistan to the expert working group on veterinary drugs. (M-282)
	Decision: - The member from M/o Food, Security informed that Pakistan has been declared as H5N1 free country. After deliberation, the Group observed that at this stage it would be premature to restrict registration of such vaccines merely on this ground as availability of such vaccines for any possible out break of the disease in future has also to be taken in consideration. Moreover, being a killed vaccine, it may not carry the hazards associated with live vaccines. The Expert Working Group, therefore, recommended OTTO FLU PLUS + VAC vaccine for being me to product.	
	Decision: Registration Board referred the case to Expert Working Group on veterinary drugs for further deliberation with reference to H5N1 strain.	

b. IMPORTED VETERINARY BIOLOGICAL NOT AVAILABLE IN EXPORTING COUNTRY REFER TO VETERINARY EXPERT COMMITTEE IN 284TH MEETING OF REGISTRATION BOARD.

1.	Name and address of Importer	M/s. Vet Line International, 55/S, 1st Floor Main Shadman Market, Lahore.
	Detail of DSL	No. 60-A/DGBT/11/2015 dated 12-02-2015 renewed upto 11-02-2019
	Name and address of Manufacturer	**Product License Holder:** M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 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. **Contract Manufacturer:** M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	ITA ND+IB+EDS+COR ABC
	Diary No. Date of R& I & fee	Dy. No. 25513 Dated 21-12-2017 Rs. 100000/- Dated 21-12-2017
	Composition	Each dose contains: Newcastle disease virus, strain NDV-"SZ" La Sota……induced min. 6 log2HI with 1 dose or min. 4log2HI with 1/50 dose or min. 50PD50 Infectious bronchitis virus, strain "M-41"… induced min. 4.4 log2 HI Egg drop syndrome'76 virus, strain "B88/78"…….. induced min. 7 log2 HI Avibacteriumparagallinarum serotype A…. min. 7 log 10 CFU* before inactivation Avibacteriumparagallinarum serotype B…. min. 7 log 10 CFU* before inactivation Avibacteriumparagallinarum serotype C…. min. 7 log 10 CFU* before inactivation *Colony Forming Unit
	Pharmacological Group	Veterinary Vaccine
	Type of Form	Form-5A
	Finished Product Specification	As per Innovator.
	Shelf Life	24 months (2^0C-8^0C)
	Document Details	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 ii. Valid Legalized FSC No. 02.2/3442-4/2016 dated 10-06-2016 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Pack size	500ml (1000 doses) Bottle
	International Availability	UEMOA(West African community including 8 countries)
	Products already registered in Pakistan	Not Available.
	Remarks of the evaluator	a. The product is not available in country of origin. The firm submitted copy of certificate of registration for product issued by ITA ND+IB+EDS+COR ABC indicating that according to diagnostic data infectious coryza has not been detected in Hungary by the National Food Chain Safety Office/ Veterinary Diagnostic Directorate in the last 10 years. The vaccine is licensed for manufacture in the country of origin .e. Hungary without being used on the Hungary market. However, it can be sold freely in the countries where the vaccine has valid market authorization. b. The firm has not submitted accelerated stability data and submitted that To perform accelerated stability study is not relevant in case of veterinary immunological products. Vaccines should be stored at 2^0C-8^0C. Storage out of range is not authorized. c. The firm has requested for "As per Innovator specifications" but the Innovator is not traceable.

	Previous Decision	Registration Board decided to refer the case to expert working group on veterinary drugs regarding the non-availability of product in country of origin and advised the firm to submit accelerated stability data of 3 batches for six months (M-284)
	Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin.	
	Decision:- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.	

c. IMPORTED VETERINARY BIOLOGICALS CONSIDERED IN DIFFERENT MEETINGS OF REGISTRATION BOARD WHICH ARE NOT AVAILABLE IN EXPORTING COUNTRY.

Sr. No.	Manufacturer/ Importer	Brand Name and Composition	Remarks	Registration Board decision
1.	M/s. Ghazi Brothers, Karachi. M/s. IZO S.p.A., Via A. Bianchi 9, Brescia, Italy.	**IzovacAviflu 9** Multidose Freeze-Dried Bottle Each dose of 0.5ml of vaccine contains:- Inactivated Avian Influenza A strain H9N2……320 H.A.U. (Immunological) **(For Veterinary Use).**	New CoPP mentions that *"The product has been developed exclusively for the treatment of the conditions particularly tropical diseases, not endemic in the country of export"*	**273rd** *"Keeping in view the facts recorded above and GMP confirmation by Italian regulatory authority, Registration Board approved the product as per valid legalized CoPP and subject to compliance of Import policy for Finished Drugs".*
Decision: - Expert working group noted that the combination is me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision: Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
2.	M/s. Forward Solutions (Animal Health Company), 67 West Wood Society, Main Canal Road, Lahore **Product License Holder:** M/s FATRO S.p.A, Via Emilia, 285-40064 Ozzano Emilia (BO) Italy **Manufacturer:** M/s FATRO S.p.A, in Via Molino Emili, 2-25030 Maclodio(BS) Italy	**Olvac A+B+G** (Oil emulsion for Injection) Each dose contains:- Inactivated Newcastle disease virus….not less than $50PD_{50}$ Inactivated infectious bronchitis virus…not less than $10^{7.5}EID_{50}$ Inactivated EDS '76 Adenovirus…not less than 1000HAU Inactivated IBD virus…not less than $10^{6.5}EID_{50}$	New CoPP mentions that *"The product has been developed exclusively for the treatment of the conditions- particularly tropical diseases- not endemic in the country of export."*	**282nd** *"clarification regarding non availability of product in country of origin as per submitted CoPPs"*(Draft minutes)
Decision: - Expert working group noted that the combination is me to and the said product is not available				

in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (virus strain used etc) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin.

Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.

3.	M/s. Forward Solutions (Animal Health Company), 67 West Wood Society, Main Canal Road, Lahore **Product License Holder:** M/s FATRO S.p.A, Via Emilia, 285-40064 Ozzano Emilia (BO) Italy **Manufacturer:** M/s FATRO S.p.A, in Via Molino Emili, 2-25030 Maclodio(BS) Italy	**Olvac B+G+R** (Oil emulsion for Injection) Each dose contains: Inactivated Newcastle disease virus….not less than $50PD_{50}$ Inactivated infectious bronchitis virus…not less than $10^{7.5}EID_{50}$ Inactivated IBD virus…not less than $10^{7.0}TCID_{50}$ Inactivated Avian Reovirus…..not less than $10^{7.0}TCID_{50}$	-do-	-do-

Decision: Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (virus strain used etc) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin.

Decision: Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.

4.	M/s. Forward Solutions (Animal Health Company), 67 West Wood Society, Main Canal Road, Lahore **Product License Holder:** M/s FATRO S.p.A, Via Emilia, 285-40064 Ozzano Emilia (BO) Italy **Manufacturer** M/s FATRO S.p.A, in Via Molino Emili, 2-25030 Maclodio(BS) Italy	**Ai-Vac H9** (oil emulsion for Injection) Each dose contains: Inactivated avian influenza virus (H9N2 strain)…not less than $10^{7.5}EID_{50}$	-do-	-do-

Decision: - Expert working group noted that the combination is me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny/evaluation of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin.

Decision: Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said

purpose.				
5.	M/s. Forward Solutions 80-A, Judicial colony ThokarNiaz Baig, Lahore FATRO S.P.A – in Via Emili, 2 – 25030 – Maclodio (BS) Italy	BIO-VAC CLONE Lyophilized for suspension) Composition: Live attenuated virus of Newcastle Disease clone strain. Titre not less than 106.5 EID50	-do-	**Decision of 258th** The Registration Board cancelled the registration in name of M/s Well Pharma Lahore. The Registration Board granted the registration in name of M/s Forward Solutions Lahore as per valid legalized CoPP, as per import policy and verification of storage facilities for the vaccines.
Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (virus strain and clone used) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
6.	M/s.Saadat International Lahore. Merial Italia S.p.A Via Baviera 9 35027 NoventaPadova na (PD) Italy	**GALLIMUNE MG** (inactivated vaccine in oil adjuvant against Mycoplasma gallisepticum infections of poultry) Each dose of 0.3 ml contains: *Mycoplasma gallisepticum*, strain S6 inactivated minimum titre before inactivation 10^9 CFU. Active Immunization of healthy breeding and laying stock against mycoplasma.	New CoPP mentions that "*Formulation/combination of the product is not required for the local market as it is specially formulated to meet the importing country requirement*"	**281st** *Registration Board deferred the case and advised DBER to bring the comparison in next Registration Board meeting with already approved such cases.* **Deferred**
Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (virus strain details, relevant studies etc) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
7.	-do-	**GALLIMUNE 403 ND+IB+IBD+REO** (Inactivated vaccine in oil adjuvant against New castle disease , Infectious bronchitis, Infectious bursal disease and Avian viralArthritis). Each dose of 0.3 ml contains:-	-do-	-do-

		Newcastle disease virus (Ulster 2C strain), inactivated, minimum titre before inactivation 10^8 EID_{50} Infectious bronchitis virus (Mass 41strain), inactivated, minimum titre before inactivation $10^{6.7}$ EID_{50} Infectious bursal virus (VNJO strain), inactivated, minimum titre before inactivation $10^{5.7}CCID_{50}$ Avian viral arthritis reovirus (S1133 strain), inactivated, minimum titre before inactivation 10^7 $CCID_{50}$ Avian viral Arthritis		
Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (immunological relevance etc) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
8.	-do-	**GALLIMUNE ART** (Inactivated vaccine in oil adjuvant against Infectious Avian Rhinotracheitis Each dose of 0.3ml contains:- Avian Rhinotracheitis virus, VCO3 strain, inactivated, at least 60IPU Active immunizationof laying and breeding stocks against avian rhinotractitis	-do-	-do-
Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (immunological relevance etc) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
9.	M/s.Saadat International Lahore. License holder: Merial Italia S.p.A Via	**GALLIVAC REO** (Live freeze dried vaccine against avian viral arthritis) Each dose of 0.2 ml contains:- Avian arthritis reovirus,	-do-	-do-

	VittorPisani 16 20124 Milano Manufacturer: IZO S.r.l. a socio unico, StradaStatale 234 Km 28200, 27013 Chignolo PO Italy	S1133 strain, at least 10^4TCID_{50}		
Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (immunological relevance etc) of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
10.	M/s. Forward Solutions 80-A, Judicial colony Thokar Niaz Baig, Lahore FATRO S.P.A – in Via Emili, 2– 25030-Maclodio (BS) Italy	**IBA-VAC ST** (Lyophilized live vaccine against (Gumboro's Disease) Each dose contains: Moderately attenuated Live virus of Infectious Bursal Disease, 2512 strain: Titer: not less than 102 EID50	New CoPP mentions that *"The product has been developed exclusively for the treatment of the conditions- particularly tropical diseases- not endemic in the country of export."*	Deferred for clarification by the firm for non-availability of the formulation by the regulatory authority in the country of the origin.
Decision: - Expert working group noted that the combination is me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation of the product may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin. **Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.**				
11.	-do-	**G-OLVAC** Inactivated vaccine in oil emulsion for injection against Newcastle Disease Virus and Infectious Bursal disease Virus Strength of active ingredient Per unit contains: Inactivated Infectious bursal disease virus, NEV 39 strain and Newcastle Disease virus, LaSota strain Titer: Newcastle disease virus……not less than 108.5 EID50 Infectious Bursal disease Virus……not less than 105.5 EID50		
Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation				

(strains, immunological relevance, scientific justification etc) of the products may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin.

Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.

12.	-do-	**EDS – VAC** Inactivated vaccine in oil emulsion for injection against Egg drop syndrome 76. Inactivated EDS Titre/dose: Not less than 80 PD50/Dose for EDS Adeno like virus strain 127		

Decision: - Expert working group noted that the combination is not me to and the said product is not available in country of origin. The Working Group was of the view that process of further scrutiny / evaluation (strains, immunological relevance, scientific justification etc) of the products may be considered, once Registration Board decide upon its status with regards to the policy for products which are not on free sale in country of origin.

Decision (M-289):- Registration Board deferred the case for seeking details from the firm, before making final decision on the matter in accordance with prevailing policy, regarding free sale status of the said product in any of the reference regulatory authority prescribed by Registration Board for the said purpose.

Deferred in M-283rd Meeting

1.	Name and address of manufacturer / Applicant	M/s. Moreno Iglisias Research Laboratories (Pvt) Ltd., 21-KM, Ferozpur Road, Lahore.
	Brand Name +Dosage Form + Strength	TF MORE Water Soluble Powder
	Diary No. Date of R& I & fee	15989, 30-04-2018, 20,000/-, 23-04-2018
	Composition	Each 100gm contains:- Tylosin……...5g Erythromycin……..…6g Furaltadone…….15gm
	Pharmacological Group	ANTIBIOTIC
	Type of Form	Form -5
	Finished Product Specification	In- house
	Pack size & Demanded Price	100g, 500g, 1Kg, Box of 4 × 250g; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	ERY-TYLODON Oral Powder of M/s Nawal Pharma (Reg #073968)
	GMP status	At the time of inspection dated 12-12-2017, the different areas of premises found clean and maintained. HVAC were also installed in the sections and functional. No production activity was observed at the time of inspection.
	Remarks of the Evaluator.	Replacement of already deferred product **"TD MORE Plus Powder"** in 272nd meeting

Decision: Expert working group observed that furaltadone has strong potential of causing genotoxicity and cytotoxicity due to possible residual effects. The formulation is therefore recommended to be rejected.

Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to reject the registration application of M/s. Moreno Iglisias Research Laboratories (Pvt) Ltd., Lahore containing Furaltadone due to strong potential of causing genotoxicity and cytotoxicity due to possible residual effects.

Deferred in M-283rd Meeting.

1.	Name and address of manufacturer/ Applicant	M/s Sanna Laboratories, 1019-B, P.S.I.E Sargodha Road, Faisalabad.
	Brand Name+ dosage Form+ Strength	NCF-200 Oral water soluble powder
	Composition	Each 100g contains: Neomycin as sulphate…….12g Chlortetracycline HCl…….40g Furaltadone HCl……..30g
	Diary No. Date of R&I & fee	Dy No. 8223: 11-07-2017 PKR 20,000/-: 10-7-2017
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded price	100g, 300g, 500g, 1Kg, 5Kg, 10Kg, 25Kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	N.C. Bak by Attabak Pharma
	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 the Evaluator.	
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of this formulation since it contains furaltadone **(M-283).**
Decision: Expert working group observed that furaltadone has strong potential of causing genotoxicity and cytotoxicity due to possible residual effects. The formulation is therefore recommended to be rejected.		
Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to reject the registration application of M/s Sanna Laboratories, Faisalabad containing Furaltadone due to strong potential of causing genotoxicity and cytotoxicity due to possible residual effects.		

Deferred in M-284th Meeting

1.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group, Plot No. 2/3, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	TEF-250 Powder
	Composition	Each kg contains: Tylosin Tartrate …….. 60gm Erythromycin Thiocynate ……... 40gm Furaltadone ……150gm
	Diary No. Date of R& I & fee	11787, 11-08-2017, 20,000/-, 10-08-2017
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	100gm, 250gm, 500g, 1kg, 2.5kg 5kg, 10kg, 15kg, 20kg, 25kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	TEF Powder of M/s Alina Combine (Reg#043575)
	GMP status	Routine GMP inspection dated 07-09-2017 showed that the firm was working under satisfactory level of GMP.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of formulation **(M-284)**.
Decision: Expert working group observed that furaltadone has strong potential of causing genotoxicity and cytotoxicity due to possible residual effects. The formulation is therefore recommended to be rejected.		
Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to reject the registration application of M/s. Farm Aid Group Hattar		

containing Furaltadone due to strong potential of causing genotoxicity and cytotoxicity due to possible residual effects.

Deferred in M-284th Meeting.

1.	Name and address of manufacturer / Applicant	M/s. Farm Aid Group, Plot No. 2/3, Phase I & II, Hattar Industrial Estate, Haripur.
	Brand Name +Dosage Form + Strength	NOVA-AID LIQUID
	Composition	Each ml contains. Novaminusulfon ……..…40mg Etilefrine ……..….0.2mg Calcium Gluconate ..……100mg Magnesium Gluconate …….10mg Sodium Salicylate ……..7mg Nicotanamide ……..0.3mg Caffeine ……10mg Boric Acid ……10mg
	Diary No. Date of R& I & fee	13169, 23-08-2017, 20,000/-, 21-08-2017
	Pharmacological Group	Analgesic, Antipyretic, Antihypertensive, Cardiac Anabolite, Synergistic &Nephroprotectible
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications.
	Pack size & Demanded Price	100ml,200ml,250ml,500ml,1Liter,2.5Liter, 5Liter,10Liter,15Liter,20Liter,25Liter;Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Novafort Oral Solution of M/s Ras (Reg#079873)
	GMP status	Routine GMP inspection dated 07-09-2017 showed that the firm was working under satisfactory level of GMP.
	Remarks of the Evaluator.	Registration Board referred the case to Expert working group on Veterinary Drugs for review of formulation **(M-284).**
Decision: Expert working group observed that Novaminsulfone is a banned drug for human use for having potential of causing blood dyscrasias. The formulation is therefore recommended to be rejected for hazards associated with its possible residual effects.		
Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to reject the registration application of M/s. Farm Aid Group Hattar containing Novaminsulfone due to strong potential of causing blood dyscrasias in human.		

Deferred in M-285th Meeting

1.	Name and address of manufacturer / Applicant	M/s. Inshal Pharmaceutical Industries, Plot # 2, Street SS2, National Industrial Zone, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	NEWENT Liquid
	Composition	Each 100ml contains:- Frusemide…….2g Belladona Extract…….……..0.2g
	Diary No. Date of R& I & fee	692, 26-06-2012, Rs.12,000/-, 21-04-2015, 8000/-, (Photocopy attached) 26-06-2012
	Pharmacological Group	Diuretic
	Type of Form	Form-5
	Finished Product Specification	In house specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1Lit, 2.5Lit, 5Lit; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	FRUSIN-B Oral Liquid of AttabakPharma (Reg # 062150)
	GMP status	Panel inspection conducted on 11-05-2018 recommended for the renewal of DML and two additional sections
	Remarks of the Evaluator.	The firm has submitted revised Form-5 correcting the strength of

		Belladonna extract as per me-too reference.
	Previous decision	Deferred for submission of fee for revision of formulation **(M-283).**
	Evaluation by PEC	The firm has deposited fee challan of Rs. 20,000/- (deposit slip # 0799105) dated 03-09-2018.
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of formulation **(M-285)**.
Decision: Expert working group recommended this formulation as Belladonna Extract provides soothing and local anesthetic effect additionally.		
Decision (M-289):- Registration Board deferred the case for further deliberation on the matter.		

B. Cases Discussed in 06th meeting of Expert Working Group on Veterinary Drugs

Sr. No.	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceuticals (Private) Limited, Plot # Q-1, S.I.T.E. Kotri Sindh.
1.	Brand Name +Dosage Form + Strength	Vetzazene injection
	Composition	Each ml contains:- Diminazine Aceturate……..……105mg Antipyrine……..……131mg
	Diary No. Date of R& I & fee	1016, 06-09-2016, 20,000/-, 02-09-2016
	Pharmacological Group	Antiprotozoa
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	10ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Pronil Injection of Selmore Pharma (Reg # 029609)
	GMP status	The inspection conducted on 24-10-2017 concluded as: ―Maintenance of required quality of air and temperature as well as cleanliness of the facility, its design to facilitate cleaning was found nicely managed. The implementation of quality oversight and control over the manufacturing of drugs was found well attended by the entire team under their best capacity. **The ability of management, enthusiasm to walk with scientific standards was visible and remarkable.** The exercise to understand the entire status of compliance with emerging regulatory expectations is **under way** and will be recorded accordingly‖.
	Remarks of the Evaluator.	
	Previous decision	Deferred for the clarification regarding chemical structure/nature of antipyrine in applied formulation **(M-277).** Registration Board referred the case to Expert working group on Veterinary Drugs for review of this formulation **(M-283).**
	Evaluation by PEC	The firm was communicated to provide rationale of antipyrine in applied formulation. In response firm has submitted that **―Diminazene aceturate** is an antiprotozoal substance active against the following babesiosis (piroplasmosis) causing agents: Babesiabigemina, Babesiadivergens, Babesiabovis in cattle; Babesiacaballi and Babesiaequi in horses; Babesiaovis in sheep; Babesiacanis and Babesiagibsoni in dogs and Theileriaannulata in cattle. It is highly effective against Trypanosomacongolense and Trypanosomavivax and moderately active against Trypanosomabruceï, Trypanosomaevansi and Trypanosomaequiperdum. **Antipyrine**(phenazone) is an analgesic, a nonsteroidal anti-

		Inflammatory drug (NSAID) and an antipyretic. It reduces fever especially in case of babesiosis. • Reference: Plumb's veterinary drug hand book sixth edition (Donald.C Plumb, Pharm-D, USA) • Chemically, antipyrine is 1,2-Dihydro-1,5-dimethyl-2-phenyl-3H-pyrazol-3-one and synonyms are Phenazone and Analgesine. • The firm has submitted reference of literature which shows that antipyrine in the injection formulation acts as stabilizer and used for inflammation and fever.
	Previous Decision:	Registration Board referred the case to Expert Working Group on Veterinary drugs for review of formulation **(M-283)**.
Decision of Expert Working Group in its 5th meeting: Deferred for further evaluation with respect to withdrawal period and safety profile of antipyrine. **Decision of Expert Working Group in its 6th meeting:** *Fixed dose combination of Diminazene aceturate & Antipyrine (Phenazone) are available and marketed in countries having heamatozoons infections, where the principle of disease therapy intends requirement of 'antiprotozoal' and 'antipyratic' together for ease and convenience of use and therapeutic effect. However, withdrawal period is advised for strict observance on label when used in food producing animals. The combination is recommended for registration.*		
Decision (M-289):- Registration Board deferred the case for further deliberation on the matter.		

2	Name and address of manufacturer / Applicant	M/s. Inshal Pharmaceutical Industries, Plot # 2, Street SS2, National Industrial Zone, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	TYLO CS Injection
	Composition	Each ml contains:- Mepyramine Maleate……50mg
	Diary No. Date of R& I & fee	10, 02-08-2012, Rs.12,000/-, 15-06-2015, 8000/-, (Photocopy attached) 02-08-2012
	Pharmacological Group	Anti-Histamine
	Type of Form	Form-5
	Finished Product Specification	In house specification
	Pack size & Demanded Price	50ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	ALLERGINIL Liquid injection of Sanna Lab (Reg#069623)
	GMP status	Panel inspection conducted on 11-05-2018 recommended for the renewal of DML and two additional sections
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of this formulation **(M-283).**
Decision of Expert Working Group in its 05th meeting: Deferred for further evaluation on safety profile of Mepyramine Maleate by Dr. Mazharul Haq.		
Decision of Expert Working Group in its 06th meeting: *Mepyramine is a competitive inhibitor at H1 tissue cell histaminic receptors. It attaches with great affinity to histamine receptors, preventing the untoward effects of histamine release. The binding of mepyramine to cell receptors evokes no direct cellular reaction. Mepyramine also has some antiserotonin properties. It is useful in counteracting the action of histamine on bronchial, intestinal, uterine and vascular smooth muscle. It antagonizes the vasodilator and vasoconstrictor effects of histamine, as well as the effect of increased capillary permeability. It may be used for urticaria, oedema formation and other allergic reactions, especially those associated with Type 1 (anaphylactic) and Type IV (cell-mediated or delayed) hypersensitivity reactions. It can also be used as an adjunct to therapy in cases such as laminitis, feed engorgement, metritis and photosensitivity and a special use is made of mepyramine's initial CNS stimulatory action on recumbent cattle. It can be given as intravenous, intramuscular and subcutaneous injection in all species.*		

The formulation is available in New Zealand under the name "Antimine" (100ml multi-dose vial; Registered pursuant to the ACVM Act 1997, NoA2677) for all species from 'Ethical Agents' a family owned veterinary, agriculture and livestock specialist, in Auckland at 54 Hobill Avenue, Wiri, Auckland 2104; Tel: 0800 800 624).A formulation in combination [Pyrilamine maleate 25 mg (also called Mepyramine maleate) and Ephedrine hydrochloride 10 mg] from Vétoquinol N.-A. Inc., 2000, ch. Georges, Lavaltrie, QC, Canada J5T 3S5 in the form of sterile injectable antihistaminic solution for veterinary (DIN 02020122) use in cattle, cats, dogs, sheep and horses is available in Canada. The Mepyramine maleate based products are recommended for registration for veterinary use.

Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to approved the above mentioned product of M/s. Inshal Pharmaceutical Industries, Islamabad.

3	Name and address of manufacturer / Applicant	M/s. Inshal Pharmaceutical Industries, Plot # 2, Street SS2, National Industrial Zone, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	MINAPYRINE INJECTION
	Composition	Each ml contains:- Diminazene Aceturate……..105mg Antipyrine…..……..131mg
	Diary No. Date of R& I & fee	560, 07-06-2012, Rs.12,000/-, 15-06-2015, 8000/-,
	(Photocopy attached) 07-06-2012	
	Pharmacological Group	Analgesic, Antipyretic, Antitrypansomiasis
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50ml amber coloured glass vials; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	PRONIL INJECTION of Selmore Pharma (Reg # 029609)
	GMP status	Panel inspection conducted on 11-05-2018 recommended for the renewal of DML and two additional sections
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of this formulation **(M-283)**.

Decision of Expert Working Group in its 5th meeting: Deferred for further evaluation with respect to withdrawal period and safety profile of antipyrine.

Decision of Expert Working Group in its 6th meeting: *Fixed dose combination of Diminazene aceturate & Antipyrine (Phenazone) are available and marketed in countries having heamatozoons infections, where the principle of disease therapy intends requirement of 'antiprotozoal' and 'antipyratic' together for ease and convenience of use and therapeutic effect. However, withdrawal period is advised for strict observance on label when used in food producing animals. The combination is recommended for registration.*

Decision (M-289):- Registration Board deferred the case for further deliberation on the matter.

4	Name and address of Applicant	M/s. Mehran International, 498-C, Feroz Shah Mehta Road, Karachi.
	Detail of Drug Sale License	**Address:** M/s. Mehran International, 498-C, Feroz Shah Mehta Road, Karachi. **Validity: 0**1/08/2019 **Status:** Drug License by way of Wholesale
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co., Ltd. No.189 Taihang Street Hi-tech Zone Shijiazhuang City, Hebei China.
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co., Ltd. No.189 Taihang Street Hi-tech Zone Shijiazhuang City, Hebei China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.2588 Dated 26/01/2017
	Fee including differential fee	Rs. 100,000/- Dated 25/01/2017
	Brand Name +Dosage Form + Strength	Diminazine and Antipyrine granules for injection
	Composition	Each 2.36g bag contains:

		Diminazene …….. 1.050gm Antipyrine …….. 1.31gm
	Target Species	(for horse, cattle and sheep use)
	Finished Product Specification	Manufacturer‘s specification
	Pharmacological Group	Antiprotozoal agent
	Shelf life	3 years
	Demanded Price	De-controlled
	Pack size	2.36g
	International availability	-
	Me-too status	Diminol powder for injection of M/s Star Labs Lahore (Reg.# 017066)
	Detail of certificates attached	Original Legalized CoPP (certificate no. 2016030519) issued by *Shijiazhuang Animal Husbandry and Aquatic Product Bureau* confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO as per CoPP. The certificate remains valid until 04-03-2021
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board referred the case to Expert Working Group on Veterinary drugs for review of formulation **(M-283)**.
Decision of Expert Working Group in its 5th meeting: Deferred for further evaluation with respect to withdrawal period and safety profile of antipyrine. **Decision of Expert Working Group in its 6th meeting:** *Fixed dose combination of Diminazene aceturate & Antipyrine (Phenazone) are available and marketed in countries having heamatozoons infections, where the principle of disease therapy intends requirement of ‘antiprotozoal’ and ‘antipyratic’ together for ease and convenience of use and therapeutic effect. However, withdrawal period is advised for strict observance on label when used in food producing animals. The combination is recommended for registration.*		
Decision (M-289):- Registration Board deferred the case for further deliberation on the matter.		

5	Name and address of manufacturer/ Applicant	Zoic International Plot # 573, Sunder Industrial Estate, Lahore
	Brand Name+ dosage Form+ Strength	ANTISTRIS-Z Water Soluble Powder
	Composition	Each 1000g contains: Acetylsalicylic acid…..222g Vitamin C…….666g
	Diary No. Date of R&I & fee	Dy No. 176: 24-4-2017 PKR 20,000/-: 24-4-2017
	Pharmacological Group	Analgesic, antipyretic, anti-inflammatory with vitamin C
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded price	25g, 50g, 100g, 500g, 1000g, 5kg, 25kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Ca Super Oral Powder by Ras Pharmaceuticals
	GMP status	GMP certificate granted on the basis of inspection dated 31-1-2018
	Remarks of the Evaluator.	
	Decision of previous meeting	Deferred for clarification of compatibility of both API’s. **(M-281)**
	Evaluation by PEC	Firm has submitted that “*taking any dose of aspirin on regular basis can triple the risk of dangerous gastrointestinal bleeding and addition of vitamin C acts as an antioxidant in the stomach to decrease aspirin induced stomach damage. Taking vitamin c and aspirin together decreases the amount of stomach damage that occurs when compared to taking aspirin alone, according to research done at German University. This to prevent aspirin induced stomach damage we add vitamin C in drug*

		combination"
	Previous Decision:	Registration Board referred the case for Expert Working Group on Veterinary Drugs **(M-285)**.

Decision of Expert Working Group (06th meeting):

Generally speaking, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) rationality of combination as fixed ratio pharmaceutical products is primarily based on marketing interest, and not on therapeutic value and justification. Ascorbic acid is very unstable compound particularly when exposed to oxygen or transition elements. Protection can only be achieved either coating it with certain substances or bonding it with certain moieties. Apparently, in the given formulation (based on provided information) vitamin C does not seem to remain stable chemically. Moreover, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) have strong negative interaction when used concomitantly. Vitamin C may act as urine acidifier that may reduce the renal excretion of aspirin and resultantly may end up in its accumulation and toxicity (A negative pharmacokinetic interaction). Concurrent use of Aspirin also impedes the gastrointestinal absorption of Vitamin C. Therefore the formulation appears only the wastage of money and stress for the animal. Furthermore, use of vitamin C in animals of veterinary importance (Ruminants) is of doubtful clinical significance.

After examination and evaluation of the justification provided by the firms for FDCs, the committee observed that the data provided and available peer reviewed scientific evidences does not support the rationality of these combinations. The expert committee is not convinced by the rationality of their use in combination presented by the manufactures. These combinations show to violate scientific merits and are without adequate justification.

Decision (M-289):- Registration Board deferred the case for further deliberation on the matter.

6	Name and address of manufacturer/ Applicant	Zoic International Plot # 573, Sunder Industrial Estate, Lahore
	Brand Name+ dosage Form+ Strength	ZASPIC Water soluble powder
	Composition	Each 100g contains: Acetylsalicylic acid……..67g Vitamin C……..…..200g
	Diary No. Date of R&I & fee	Dy No. 159: 24-4-2017 PKR 20,000/-: 24-4-2017
	Pharmacological Group	Analgesic, antipyretic, anti-inflammatory with vitamin C
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in-house specification
	Pack size & Demanded price	100g, 500g, 1kg, 5kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	STR Acetyl-C Powder by Star Labs, Lahore
	GMP status	GMP certificate granted on the basis of inspection dated 31-1-2018
	Remarks of the Evaluator.	
	Decision of previous meeting	Deferred for clarification of compatibility of both API's. (**M-281)**
	Evaluation by PEC	Firm has submitted that "*taking any dose of aspirin on regular basis can triple the risk of dangerous gastrointestinal bleeding and addition of vitamin C acts as an antioxidant in the stomach to decrease aspirin induced stomach damage. Taking vitamin c and aspirin together decreases the amount of stomach damage that occurs when compared to taking aspirin alone, according to research done at German University. This to prevent aspirin induced stomach damage we add vitamin C in drug combination*"
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of formulation**(M-285)**.

Decision of Expert Working Group (05th meeting): Deferred for submission of product development data and rationale of applied formulation.

Decision (06th meeting):-

Generally speaking, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) rationality of combination as fixed ratio pharmaceutical products is primarily based on marketing interest, and not on therapeutic value and justification. Ascorbic acid is very unstable compound particularly when exposed to oxygen or transition elements. Protection can only be achieved either coating it with certain substances or bonding it with certain moieties. Apparently, in the given formulation (based on provided information) vitamin C does not seem to remain stable chemically. Moreover, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) have strong negative interaction when used concomitantly. Vitamin C may act as urine acidifier that may reduce the renal excretion of aspirin and resultantly may end up in its accumulation and toxicity (A negative pharmacokinetic interaction). Concurrent use of Aspirin also impedes the gastrointestinal absorption of Vitamin C. Therefore the formulation appears only the wastage of money and stress for the animal. Furthermore, use of vitamin C in animals of veterinary importance (Ruminants) is of doubtful clinical significance.

After examination and evaluation of the justification provided by the firms for FDCs, the committee observed that the data provided and available peer reviewed scientific evidences does not support the rationality of these combinations. The expert committee is not convinced by the rationality of their use in combination presented by the manufactures. These combinations show to violate scientific merits and are without adequate justification.

Decision: Registration Board deferred the case for further deliberation on the matter.

7	Name and address of manufacturer / Applicant	"M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur"
	Brand Name +Dosage Form + Strength	Meprax Injection
	Composition	Each ml Contains: Mepyramine maleate ….. 50mg
	Diary No. Date of R& I & fee	Dy.No 23797 dated 12-12-2017 Rs. 20,000 Dated 08-12-2017
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50ml
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength and dosage form)	MEPRAWITS INJECTION Of M/s. WIMITS PHARMACEUTICALS, (Reg.#078303)
	GMP status	Last GMP inspection conducted on 13-09-2018 and 14-09-2018 recommending the renewal of DML
	Remarks of the Evaluator	
	Decision of Expert Working Group in its 06th meeting: *Mepyramine is a competitive inhibitor at H1 tissue cell histaminic receptors. It attaches with great affinity to histamine receptors, preventing the untoward effects of histamine release. The binding of mepyramine to cell receptors evokes no direct cellular reaction. Mepyramine also has some antiserotonin properties. It is useful in counteracting the action of histamine on bronchial, intestinal, uterine and vascular smooth muscle. It antagonizes the vasodilator and vasoconstrictor effects of histamine, as well as the effect of increased capillary permeability. It may be used for urticaria, oedema formation and other allergic reactions, especially those associated with Type 1 (anaphylactic) and Type IV (cell-mediated or delayed) hypersensitivity reactions. It can also be used as an adjunct to therapy in cases such as laminitis, feed engorgement, metritis and photosensitivity and a special use is made of mepyramine's initial CNS stimulatory action on recumbent cattle. It can be given as intravenous, intramuscular and subcutaneous injection in all species.* *The formulation is available in New Zealand under the name "Antimine" (100ml multi-dose vial; Registered pursuant to the ACVM Act 1997, NoA2677)for all species from 'Ethical Agents' a family*	

	owned veterinary, agriculture and livestock specialist, in Auckland at 54 Hobill Avenue, Wiri, Auckland 2104; Tel: 0800 800 624).A formulation in combination [Pyrilamine maleate 25 mg (also called Mepyramine maleate) and Ephedrine hydrochloride 10 mg] from Vétoquinol N.-A. Inc., 2000, ch. Georges, Lavaltrie, QC, Canada J5T 3S5 in the form of sterile injectable antihistaminic solution for veterinary (DIN 02020122) use in cattle, cats, dogs, sheep and horses is available in Canada. *The Mepyramine maleate based products are recommended for registration for veterinary use.*	
Decision: Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to approved the above mentioned product of M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur.		
8	Name and address of manufacturer / Applicant	M/s Mylab Pvt Ltd. Khankah Sharif Bahawalpur
	Brand Name +Dosage Form + Strength	Aspire-C Water Soluble Powder
	Composition	Each gm Contains: Acetylsalicylic Acid…67mg Vitamin C…200mg
	Diary No. Date of R& I & fee	Dy No. 23783: 12-12-2017 PKR 20,000/-: 08-12-2017
	Pharmacological Group	Analgesic and vitamin
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	500g, 1000g, 5000g
	Approval status of product in Reference Regulatory Authorities.	N.A
	Me-too status	Gesix-C Water Soluble Powder by Prix Pharma (Reg#043286)
	GMP status	Last GMP inspection report dated 13th and 14th September, 2018 recommended renewal of DML and grant of additional sections.
	Remarks of the Evaluator[3].	The applied formulation is previously referred to veterinary evaluation committee by Registration Board
	Decision of Expert Working Group in its 06th meeting: *Generally speaking, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) rationality of combination as fixed ratio pharmaceutical products is primarily based on marketing interest, and not on therapeutic value and justification. Ascorbic acid is very unstable compound particularly when exposed to oxygen or transition elements. Protection can only be achieved either coating it with certain substances or bonding it with certain moieties. Apparently, in the given formulation (based on provided information) vitamin C does not seem to remain stable chemically. Moreover, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) have strong negative interaction when used concomitantly. Vitamin C may act as urine acidifier that may reduce the renal excretion of aspirin and resultantly may end up in its accumulation and toxicity (A negative pharmacokinetic interaction). Concurrent use of Aspirin also impedes the gastrointestinal absorption of Vitamin C. Therefore the formulation appears only the wastage of money and stress for the animal. Furthermore, use of vitamin C in animals of veterinary importance (Ruminants) is of doubtful clinical significance.* *After examination and evaluation of the justification provided by the firms for FDCs, the committee observed that the data provided and available peer reviewed scientific evidences does not support the rationality of these combinations. The expert committee is not convinced by the rationality of their use in combination presented by the manufactures. These combinations show to violate scientific merits and are without adequate justification.*	
Decision: Registration Board deferred the case for further deliberation on the matter.		
9	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	Vital-C Oral Powder
	Composition	Each 100g powder contains: Vitamin C……20g Acetyl Salicylic……20g Vitamin K3……2.5g
	Diary No. Date of R& I & fee	14-11-2016, Dy. No.2185, Rs.20,000/-, 10-11-2016

	Pharmacological Group	Analgesic and Antipyretic (NSAIDs)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5Kg, 5Kg, 10Kg,20Kg, 25kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	C-Plus Powder of M/s. Intervac Pharma (Reg#046598)
	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.
	Remarks of the Evaluator.	
	Decision of Exper Working Group in its 06th meeting: *Generally speaking, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) rationality of combination as fixed ratio pharmaceutical products is primarily based on marketing interest, and not on therapeutic value and justification. Ascorbic acid is very unstable compound particularly when exposed to oxygen or transition elements. Protection can only be achieved either coating it with certain substances or bonding it with certain moieties. Apparently, in the given formulation (based on provided information) vitamin C does not seem to remain stable chemically. Moreover, Acetylsalicylic acid (Aspirin) and Ascorbic acid (vitamin C) have strong negative interaction when used concomitantly. Vitamin C may act as urine acidifier that may reduce the renal excretion of aspirin and resultantly may end up in its accumulation and toxicity (A negative pharmacokinetic interaction). Concurrent use of Aspirin also impedes the gastrointestinal absorption of Vitamin C. Therefore the formulation appears only the wastage of money and stress for the animal. Furthermore, use of vitamin C in animals of veterinary importance (Ruminants) is of doubtful clinical significance.* *The presence of vitamin K3 may influence the oxidative susceptibility of vitamin C and its requirement as well. The use of vitamin K3 in combination with aspirin is more irrational and has no therapeutic value. Rather it may enhance the adverse effects. As aspirin inhibits the synthesis of vitamin K dependent clotting factors. With the use of aspirin, prothrombin synthesis is impaired and leads to hypo-prothrombin-emia.* *The provided info on the formulations is ambiguous. For example the water solubility of the Menadione (vitamin K3) is pharmaceutical form specific. Ascorbic acid does not have clinically validated data on aspirin induced gastro-protection in animals as argued by the firms. However, some antisecretory and/or antacid generics might have some clinical value without any significant influence on pharmacokinetic profile.* *After examination and evaluation of the justification provided by the firms for FDCs, the committee observed that the data provided and available peer reviewed scientific evidences does not support the rationality of these combinations. The expert committee is not convinced by the rationality of their use in combination presented by the manufactures. These combinations show to violate scientific merits and are without adequate justification.*	
Decision:- Registration Board deferred the case for further deliberation on the matter.		
10.	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	LIFER ORAL SOLUTION
	Composition	Each ml contains: L-Carnitine……..50 mg BetainHCl……..20 mg Inositol……7 mg Choline chloride……..100 mg Sorbitol……200 mg Magnesium sulphate……10 mg
	Diary No. Date of R& I & fee	06-03-2017, Dy. No.3442, Rs.20,000/-, 24-02-2017

	Pharmacological Group	Electrolyte / Amino acid
	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	Hepabar Oral Liquid of M/s Baariq Pharma (Reg#080733)
	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.
	Remarks of the Evaluator.	
	Decision of Expert Working Group in its 06th meeting: *The principal component of the product L-Carnitine is a vitamin-like substance that is synthesized in the body of animals through a metabolic process involving several cofactors (lysine and methionine), four vitamins (vitamin C, niacin, vitamin B12 and choline) and reduced iron. Despite increased hepatic carnitine concentration around calving, insufficient endogenous carnitine synthesis might contribute to fatty liver-development in peri-parturient dairy. Carnitine mediates energy production and is beneficial in detoxification of aflatoxins. Higher animals, including mammals, can synthesize carnitine. However, recent studies have indicated that the biosynthesis of carnitine may be limited or inadequate in certain animals. The demand for carnitine during the suckling period may exceed the capacity for its synthesis. Although carnitine has been studied in humans and under laboratory conditions for many years, its effectiveness in promoting the performance and well-being of domestic animals has only recently received attention. A role for carnitine in animal species has been established. The other components of the products (including an array of amino acids, and sugars) also support the Carnitine synthesis; thus having the fortifying action on availability of the principal molecule for enhanced metabolism, energy production and cellular detoxification.*	
Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to approved the above mentioned product of M/s. Decent Pharma, Rawat.		

11.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt Ltd. 542-A & B, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Furol Powder
	Composition	Each gm Contains: Furazolidone…….950mg.
	Diary No. Date of R& I & fee	Dy. No.290; 7-9-2015; Rs.20,000/- (7-9-2015)
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specification	Mfg
	Pack size & Demanded Price	20gm, 50gm, 100gm, 250gm, 500gm, 1000gm, 2.5kg, 5kg 10Kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Furasym Powder by Syman Pharmaceuticals Reg # 023435
	GMP status	New Section Veterinary Powder (General & General Antibiotic)
	Remarks of Evaluator	
	Decision (06th meeting): Expert working group, as already deliberated in its 05th meeting held on 27-12-2018, observed that **Furazolidone** has strong potential of causing genotoxicity and cytotoxicity due to possible residual effects. The formulation is therefore recommended to be rejected.	
Decision (M-289):- Keeping in view the recommendation of Expert Working Group on Veterinary Drugs, Registration Board decided to reject the registration application of M/s Izfaar Pharmaceutical Pvt Ltd, Lahore containing Furazolidone due to strong potential of causing genotoxicity and cytotoxicity due to possible residual effects.		

Case No.01:- REQUEST OF M/S. PAK CHINA INTERNATIONAL, KARACHI FOR CHANGE OF MANUFACTURING SITE OF THEIR ALREADY REGISTERED PRODUCT.

M/s. Pak China International, 233, Sunny Plaza Hasrat Mohani Road, Karachi has applied for change of manufacturing site of their following already registered human product, as per details given below. Due to several changes in modern technology in plant of existing manufacturer M/s. Furen Pharmaceutical Group Co. Ltd. China have stopped the manufacturing of Metronidazole Injection 100ml and are unable to supply the registered product Metronidazole Injection 100ml to Pakistan market.

S. No.	Reg. No.	Name of Product(s) with Composition.	Existing Manufacturer/ Exporter.	New proposed Site(s).
1.	013267	Metronidazole Injection 100ml Per single dose glass vial contains:- Metronidazole……0.5gm	**Manufacturer:** M/s. Furen Pharmaceutical Group Co. Ltd. China. **Exported by:** M/s. Ninhua Group Co. Ltd. 21, Jiangxia Street, Ningbo 315000 P.R. China.	**Manufacturer and product License Holder:** M/s. Cisen Pharmaceutical Co. Ltd., Haichuan Road, Jining High & New Technology Industrial Development Zone, Jining, Shandong Province, China. **Exported by:** M/s. Ninhua Group Co. Ltd. 21, Jiangxia Street, Ningbo P.R. China.

Firm has deposited required fee of Rs.100,000/- and submitted following supporting documents:-

(i) Revised Form 5A.
(ii) Copy of initial registration letter.
(iii) Copy of change of manufacturer and exporter.
(iv) Copy of change of exporter.
(v) Copy of last renewal receiving.
(vi) NOC from previous manufacturer i.e. M/s. Furen Pharmaceutical Group Co. Ltd. China.
(vii) Revised Original & legalized CoPP's and GMP for new manufacturing site.
(viii) Credential of new manufacturing site.
(ix) Copy of distribution agreement.
(x) Site master plan of the manufacturer.

Decision: **Registration Board approved the above changes in respect of registered products Metronidazole Injection 100ml (Reg.No. 013267), subject to policy for imported finished drug registration. Other terms and conditions remain the same.**

Case No.02:- Registration of Drugs under the Drugs Act, 1976-Inspection Reports of Manufacturer Abroad.

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.

S. No.	Name of Importer/ Manufacturer & meeting number	Name of Drug/ Composition/ Shelf Life	Panel of Inspector(s)/ Date of inspection
1.	M/s. Mehran International, Pliva Avenue Hume Road	**(i)** Ondansetron injection 8mg/4ml Each 4ml ampoule contains:- Ondansetron Hydrochloride eq. to	(i) Dr. Fakhruddin Aamir, Additional Director, Drug

	Near World Map Karachi./ **Manufacturer & Marketing Authorization Holder:-** M/s. Cisen Pharmaceutical Co. Ltd. Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining, Shadong, China. **Exported by:** M/s. Ninhua Group Co. Ltd. 21, Jiangxia Street, Ningbo P.R. China.	Ondansetron…….8mg *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:* *Real-time stability study data (conducted as per Zone IV-A) of 3 batches 17051, 17052 and 17053 which were manufactured in May 2017.* *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).* *Test* / *Submitted specification* / *USP specification* *pH* / *3 – 4* / *3.3 – 4* *Assay* / *93 – 107%* / *95 – 105%* Shelf Life 03 years	Regulatory Authority of Pakistan, Islamabad. (ii) Mr.Zaheer-ud-Din Muhammad Babar, Deputy Director, Drug Regulatory Authority of Pakistan, Islamabad. 7th& 8th December, 2018
	-do-	**(ii)** Ofloxacin infusion 200mg/100ml Each 100ml infusion bottle contains:- Ofloxacin…200mg/100ml Shelf Life 03 years	
	-do-	**(iii)** Ciprofloxacin infusion 200mg/100ml Each 100ml infusion bottle contains:- Ciprofloxacin lactate eq to ciprofloxacin……200mg Shelf Life 03 years	
	-do-	**(iv)** Omipen Injection 40mg Each vial contains:- Omeprazole sodium eq to omeprazole (lyophilized powder)…….40mg	

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 ***M/s 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.

Registration Board in its 288th meeting decided as:

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 at Sr. No. 1-3 "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.***

In response the firm has deposited fee of Rs.100,000 x 3 = Rs.300,000/- and submitted following

supporting documents:-

(i) Revised Form 5A of above products for Sr. No.1-3.
(ii) Original & legalized CoPP's and GMP for new manufacturing site of above products.
(iii) Credential of new manufacturing site M/s. Cisen Pharmaceutical Co. Ltd., Haichuan Road, Jining High & New Technology Industrial Development Zone, Jining, Shandong Province, China.
(iv) Copy of distribution agreement.
(v) Site master plan of the manufacturer.

Decision: **Approved processing of issuance of registration letter for product "*Ondansetron Injection 8mg/4ml, Ofloxacin Infusion 200mg/100ml, Ciprofloxacin Infusion 200mg/100ml*" to be manufactured at "M/s. Cisen Pharmaceutical Co. Ltd., Haichuan Road, Jining High & New Technology Industrial Development Zone, Jining, Shandong Province, China." as per the COPP and in accordance with the recommendation of said site by nominated inspection panel.**

Case.No.03:- Request of M/s. Medinet Pharmaceuticals, Rawalpindi for Change of Name of manufacturer for registered product Anfotericina Fada Injection (Reg.No. 033128).

M/s. Medinet Pharmaceuticals, Rawalpindi requested for change of name of manufacturer for registered products the details are as under. The case was presented in 286th meeting of Registration Board.

S.#	Regn. No.	Existing Name/ Composition	Existing Name of manufacturer	Proposed Name of manufacturer & Market authorization holder (as per CoPP)	Initial registration with renewal	Remarks/ Diary No. R&I
I	II	III	IV	V	VI	VII
1.	031391	Varedet Injection Each vial contains:- Vancomycin HCI.....500mg	M/s. FADA Pharma S.A., Argentina.	Manufacturer & Product License Holder:- M/s. Laboratorio Inernacional Argentino S.A., 1641, Tabare St. C.A.B.A. Argentine Republic.	27-7-2004 Last renewal submitted on 17-7-2014	Dy. No. 7355 R&I dated 27-02-2018.
2.	031392	Varedet Injection Each vial contains:- Vancomycin HCI.....1000mg	-do-	-do-	27-7-2004 Last renewal submitted on 17-7-2014	-do-
3.	031393	Duvig Injection Each vial contains:- Dobutamine HCI…….250mg	-do-	-do-	27-7-2004 Last renewal submitted on 17-7-2014	-do-
4.	033128	Anfotericina Fada Injection Each vial contains:- Amphotericin B…….50mg	-do-	M/s. Laboratorio Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina.	03-12-2004 Last renewal submitted on 21-11-2014	-do-

Firm has deposited fee of Rs.5,000x4=20,000/- & submitted following supporting documents:-

i) Copies of registration letters.
ii) Copies of renewal status.
iii) Original & legalized CoPP issued by Argentian Authority.

iv) Original & Legalized GMP issued by Argentian Authority.
v) Copy of Drug Sale License.
vi) Copy of change of corporate name amendment of the articles in corporation.

It is pertinent to mentioned that the firm has requested for change of name of manufacturer for all the products from M/s. FADA Pharma S.A., Argentina to M/s. Laboratorio Inernacional Argentino S.A., 1641, Tabare St. C.A.B.A. Argentine Republic. However, as per CoPP of product at Sr. No.4, the name and address of manufacturer is mentioned as M/s. Laboratorio Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina. which is different from the one requested by the firm. Similarly the address of the manufacturer abroad was not mentioned on initial registration letter.

Case was presented before Registration Board in its 283rd meeting & Board decided as follow;

"Registration Board deferred the case for confirmation of address of manufacturer from previous import clearance documents in order to ascertain that the manufacturing site(s) is/are the same."

The firm has now provided previous import documents wherein it can be confirmed that, for products at Sr.No.1-3, the manufacturing site remains the same.

Decision: Registration Board decided as follow;

a. For products at Sr.No.1-3, approved the change in name of manufacturer from M/s. FADA Pharma S.A., Argentina to M/s. Laboratorio Inernacional Argentino S.A., 1641, Tabare St. C.A.B.A. Argentine Republic on same terms and conditions.
b. For product at Sr.No.4, deferred the case for seeking clarification from the firm regarding the address/status of manufacturer

With reference to above decision for the product Anfotericina Fada Injection (Reg.No.033128)(at Sr.no.04). The firm has submitted as under:-

1. As already informed that there are 5 plants of Labortorio Internacional Argentino S.A in Argentina including the following mentioned in the GMP and COPP.
   - Plant at 1641, Tabare St.C.A.B.A Argentina Republic.
   - Plant at 4444, 12 de Octubre Av., Quilmes Buenos Aires, Argentina.
2. The drug under question Anfotericina Fada Injection 500mg (Amphotericin B) is manufactured at plant 4444, 12 de Octubre Av., Quilmes Buenos Aires, Argentina and there is no change in the manufacturing site of the drug.
3. The company legal address is at 1641, Tabare St. C.A.B.A. Argentina republic which is mentioned in the invoices as being the legal and business address of the company. This address is written in the export documents of all the products in the place of manufacturing site which made confusion in the change of the address.
4. Since GMP and COPP are issued by the Regulatory body of the country (Argentina), therefore, address of the representative manufacturing site is mentioned on the GMP and COPP.

Sr. NO.	Product	Address as per GMP	Address as per COPP	Address as per Import Clearance Invoice
1.	Anfotericina Fada Injection 50mg (Reg.No. 033128)	M/s Laboratoria Internacional Argentino S.A 4444, 12 de Octubre Av., Quilmes Buenos Aires, Argentina.	M/s Laboratoria Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina	Not Provided

The firm has not provided previous import documents so it cannot be confirmed that, for this product, the manufacturing site remains the same or different.

Decision: Registration Board deferred the case for further deliberation.

Case No.04:- Request of M/s Mukhtar Enterprises for the change of Specifications from USP to In-house of their already registered products.

M/s Mukhtar Enterprises, Lahore has requested for the change of Specifications from USP to IN-House of their already registered two products.

Sr. No	Reg No.	Product	Manufacturer and Product license Holder
1	085257	Vancomycin 500mg Injection vial Powder for concentrate for solution for IV infusion (USP Specifications)	M/s Xellia Pharmaceutical ApS Dalslandsgade 11, 2300 Copenhagen S Denmark
2	085258	Vancomycin 1000mg Injection vial Powder for concentrate for solution for IV infusion (USP Specifications)	-do-

The firm has applied In-House Specifications in the dossier (application).

The firm (M/s Xellia, Denmark) has submitted that the product was initially developed according to the USP monograph (because the product is officially available in USP monograph). In order to market the product in European Union, the product must follow the Ph.Eur regulations and test methods. This product is not officially available in Ph.Eur monograph, henceforth the product was developed through In-house method and finished product tests or parameters were analysed using Ph.Eur testing methods only as mentioned in the Pharmacopeia reference column of Finish Product Specifications.

A comparison has been made between both specifications.

Sr. No.	Tests	Xellia Specifications	USP specifications
1	Chromatographic Purity (HPLC) Vancomycin B	NLT 92%	NLT 88%
2	Bacterial Endotoxins	LT 0.25IU/mg	NMT 0.33EU/mg activity
3.	Assay	95%-105%	90%-115%
4.	pH	3-5	3-5
5.	Sub-Visible Particles Diameter _>10um Diameter _>25um	NMT 6000 Particles/Vial NMT 600 Particles/Vial	NMT 6000 Particles/Vial NMT 600 Particles/Vial
7.	Water	NMT 3%	NMT 5%
9.	Impurities	NMT 1.8%	NMT 4%

Decision: Registration Board approved in house specifications (Xellia Specifications) for above products as these are more stringent than USP.

Registration Board deferred rest of agenda due to paucity of time.
The meeting ended with the vote of thanks to and from the Chair.